

Act) nor shall there be any limitation of liability of Indemnifying Persons in connection with any of such rights of the Indemnified Persons (i) to bring any claim, demand, suit or cause of action otherwise available to the Indemnified Persons as a result of an Indemnifying Person's intentional fraud or intentional fraudulent misrepresentation or (ii) to enforce any Order of a Court of competent jurisdiction which finds or determines that the Indemnifying Person had defrauded intentionally or made an intentional fraudulent misrepresentation in connection with this Agreement and the transactions contemplated hereby.

#### 7.6. Assertion of Claims

No claim shall be brought under Sections 7.3 or 7.4 hereof unless the Indemnified Persons, or any of them, at any time prior to the applicable Survival Date, provide the Indemnifying Persons with (a) written notice of the existence of any such claim, specifying the nature and basis of such claim and the amount thereof, to the extent known, or (b) written notice pursuant to this Section 7.6 of any Third Party Claim, the existence of which might give rise to such a claim; provided, that, the failure so to provide such notice to the Indemnifying Persons will not relieve the Indemnifying Persons from any liability which they may have to the Indemnified Persons under this Agreement or otherwise, except to the extent that the Indemnifying Person reasonably demonstrates that such failure results in the loss or compromise of any rights or defenses of the Indemnifying Persons and that the Indemnifying Persons were not otherwise aware of such action or claim. Upon the giving of such written notice as aforesaid, the Indemnified Persons, or any of them, shall have the right to commence legal proceedings prior or subsequent to the Survival Date for the enforcement of their rights under Section 7.3 or 7.4 hereof, as the case may be, resulting from the assertion of liability by third parties (each, a "Third Party Claim") shall be subject to the following terms and conditions:

(a) If an Indemnified Person gives notice to the Indemnifying Person pursuant to Section 7.6 of the assertion of a Third Party Claim, the Indemnifying Person shall be entitled to assume the defense of such Third Party Claim using counsel reasonably satisfactory to the Indemnified Person; provided, that, the Indemnifying Person shall not be entitled to assume the defense of such Third Party Claim if (i) the Indemnifying Person is also a Person against whom the Third Party Claim is made and the Indemnified Person determines in good faith that (A) joint representation would be inappropriate, or present a conflict of interest, or (B) there are legal defenses available to the Indemnified Party that are different from or in addition to those available to the Indemnifying Person; (ii) the Indemnifying Person fails to provide reasonable assurance to the Indemnified Person of its financial capacity to defend such Third Party Claim and provide indemnification with respect to such Third Party Claim; or (iii) the Third Party Claim seeks, or is reasonably likely to seek or result in, the imprisonment of, the imposition of a criminal penalty or fine against, or the imposition of an equitable remedy with respect to, the Indemnified Persons. Subject to the foregoing, after notice from the Indemnifying Person to the Indemnified Person of its election to assume the defense of such Third Party Claim, the Indemnifying Person shall, so long as it diligently conducts such defense, (i) not be liable to the Indemnified Person under this Section 7.6 for any fees of other counsel or any other expenses with respect to the defense of such Third Party Claim subsequently incurred by the Indemnified Person in connection with the defense of such Third Party Claim and (ii) have full control over the conduct of such proceeding. If the Indemnifying Person assumes the defense of a Third party Claim, no compromise or settlement of such Third Party Claim may be effected by the Indemnifying Person without the Indemnified

Person's written consent unless (A) there is no finding or admission of any violation of Law or any violation of the rights of any Person; (B) the sole relief provided is monetary damages that are paid in full by the Indemnifying Person; and (C) the Indemnified Person shall have no liability or obligation (including without limitation any obligation to take or to refrain from taking any action) with respect thereto. If notice is given to an Indemnifying Person of the assertion of any Third Party Claim and the Indemnifying Person does not, within ten (10) days after such notice is received by the Indemnifying Person, give notice to the Indemnified Person of its election to assume the defense of such Third Party Claim, the Indemnifying Person will be deemed to have waived the right to defend such Third Party Claim and shall be bound by any determination made in such Third Party Claim or any compromise or settlement effected by the Indemnified Person.

(b) Notwithstanding the foregoing, if an Indemnified Person determines in good faith that there is a reasonable probability that a Third Party Claim, if determined adversely, will materially adversely affect it or its Affiliates other than as a result of monetary damages for which it would be entitled to indemnification under this Agreement, the Indemnified Person may, by notice to the Indemnifying Person, assume the exclusive right to defend, compromise or settle such Third Party Claim, but the Indemnifying Person will not be bound by any determination of any Third Party Claim so defended for the purposes of this Agreement or any compromise or settlement effected without its consent (which shall not be unreasonably withheld).

(c) Notwithstanding the provisions of Section 8.11, the Sellers hereby consent to the non-exclusive jurisdiction of any court in which a proceeding in respect of a Third Party Claim is brought against any Purchaser Indemnified Person for purposes of any claim that a Purchaser Indemnified Person may have under this Agreement with respect to such proceeding or the matters alleged therein and agree that process may be served on the Sellers with respect to such a claim anywhere in the world.

(d) With respect to any Third Party Claim subject to indemnification under this Section 7.6: (i) both the Indemnified Person and the Indemnifying Person, as the case may be, shall keep the other Person fully informed of the status of such Third Party Claim and any related proceedings at all stages thereof where such Person is not represented by its own counsel, (ii) the parties agree (each at its own expense) to render to each other such assistance as they may reasonably require of each other and to cooperate in good faith with each other in order to ensure the proper and adequate defense of any Third Party Claim and (iii) the parties agree to cooperate in such a manner as to preserve in full (to the extent possible) the confidentiality of all Confidential Information and the attorney-client and work-product privileges.

#### 7.7. Materiality Disregarded

. For all purposes of this Article VII, the representations and warranties of the Company shall not be deemed qualified by, and shall be read as if deleted therefrom were, any references to materiality or to the defined term "Material Adverse Effect."

#### 7.8. Insurance Proceeds

. Payments by an Indemnifying Person pursuant to this Article VII in respect of any Loss shall be limited to the amount of any liability or damage that remains after deducting therefrom

any insurance proceeds and any indemnity, contribution or other similar payment actually received by the Indemnified Person (or the Company) in respect of any such claim after deducting all related reasonable and out-of-pocket attorneys' fees, expenses and other costs of recovery (including any deductible amount) and any resultant increase in insurance premiums. The Indemnified Person shall use its commercially reasonable efforts to recover under insurance policies or indemnity, contribution or other similar agreements for any Losses prior to seeking indemnification under this Agreement.

#### 7.9. Loss Exclusions

. In no event shall any Indemnifying Person be liable to any Indemnified Person for any punitive damages relating to the breach or alleged breach of this Agreement or any Transaction Documents except to the extent awarded by a court of competent jurisdiction to a third party; *provided*, that the foregoing shall not limit any Indemnifying Person's liability for damages that were probable or reasonably foreseeable as of a Closing Date and were a direct result of a breach or alleged breach of this Agreement or any of the Transaction Documents.

#### 7.10. Exclusive Remedies

. The parties (other than the Sellers' Representative) acknowledge and agree that their sole and exclusive remedy with respect to any and all claims (other than claims pursuant to Section 7.5(d) of this Agreement) for any breach of any representation, warranty, covenant, agreement or obligation set forth herein or otherwise relating to the subject matter of this Agreement, shall be pursuant to the indemnification provisions set forth in this Article VII. In furtherance of the foregoing, each party (other than the Sellers' Representative) hereby waives, to the fullest extent permitted under Law, any and all rights, claims and causes of action for any breach of any representation, warranty, covenant, agreement or obligation set forth herein or otherwise relating to the subject matter of this Agreement it may have against the other parties hereto and their Affiliates and each of their respective Representatives arising under or based upon any Law, except pursuant to the indemnification provisions set forth in this Article VII. Nothing in this Article VII shall limit any Person's right to seek and obtain any equitable relief to which any Person shall be entitled.

#### 7.11. Payments

(a) Any payment due by the Sellers or any of them to a Purchaser Indemnified Person in respect of Losses recoverable under this Article VII (subject to the limitations of Section 7.5) shall be made from the following sources and in the following order of priority (i) first, from the Escrow Fund pursuant to the terms of the Escrow Agreement, and (ii) second, to the extent such Losses exceed the Indemnity Escrow Amount and are attributable to Excluded Claims, from the Sellers on a pro rata basis according to the Merger Consideration received by each such Seller. For the avoidance of doubt, Purchaser shall be permitted to recover Losses from the full amount available in the Escrow Funds even though the liability of the Sellers is several and not joint and the disbursement of any remaining Escrow Funds shall be handled in accordance with Section 2.5(d).

(b) The Escrow Agent shall distribute to the Payments Administrator as directed by the Sellers' Representative from the Escrow Fund, subject to the terms and conditions of the Escrow Agreement on the date that is eighteen (18) months after the Closing Date (the "Escrow Period"), all of the then remaining Indemnity Escrow Amount in excess of the sum of any amounts with respect to (i) which a Purchaser Indemnified Person is entitled to, but has not yet received, indemnification, pursuant to this Article VII, and (ii) any pending claims for indemnification as to which the Purchaser Indemnified Persons have timely delivered notice of claims as of such date as provided in this Agreement. The Payments Administrator shall remit such remaining Indemnity Escrow Amount to the Sellers in accordance with Schedule 2.5(d) (as delivered and updated pursuant to Section 2.5(d), including Company Options subject to Option Cancellation Agreements); provided that in the event the Merger Consideration included any payments in consideration for cancellation of Company Options that were not exercised, the Sellers' Representative shall direct the Escrow Agent to deliver such portion of the Escrow Fund allocable to such payments to the Surviving Company and the Surviving Company shall remit such portion of the Escrow Fund to such holders, less applicable withholding taxes.

#### 7.12. No Double Recovery

. A Person shall not be required to indemnify an Indemnified Person from or against a Loss to the extent such Indemnified Person has already been fully reimbursed, indemnified and held harmless under this Agreement on account of the same Loss.

### ARTICLE VIII MISCELLANEOUS

#### 8.1. Termination

(a) This Agreement may be terminated and the transactions contemplated hereby may be abandoned at any time prior to Closing by written notice delivered by the terminating party to the other party:

(i) By Purchaser upon Company's failure to achieve any of the milestones set forth in Section 6.1(a), it being understood that the determination of whether Company has achieved such milestones shall be determined by the Purchaser at its sole discretion;

(ii) By Purchaser upon the Company's breach of Section 5.5;

(iii) By mutual consent duly authorized by the Boards of Purchaser and the Company at any time prior to Closing;

(iv) By the Company, if the Purchaser's HSR Filing has not been submitted within five (5) Business Days after the Final Milestone Date;

(v) By either Purchaser or the Company, if the Closing shall not have been consummated on or before the Outside Date; provided, however, that except



as set forth in Section 8.1(c) below, if (A) an HSR Filing has been timely submitted but the waiting period(s) under the HSR Act applicable to the transactions to be consummated have not expired or been terminated and/or (B) Purchaser receives a Second Request, such date shall be extended to a date as appropriate to allow for the waiting period(s) to expire or be terminated or as necessary to respond to such Second Request in accordance with the provisions of Section 5.6(c)(ii), as applicable, but in any event not later than October 1, 2020; or

(vi) By either the Company or Purchaser if a Governmental Authority (including pursuant to the HSR Act) shall have issued an order, decree or ruling or taken any other action (including the failure to have taken an action), in any case having the effect of permanently restraining, enjoining or otherwise prohibiting the Closing, which order, decree, ruling or other action is final and non-appealable.

(b) If one or more of the Performance Milestones has not been achieved in accordance with Section 6.1(b) and is not waived by the Purchaser by the Outside Date, this Agreement shall terminate automatically on the Outside Date with no further action by either party.

(c) In the event of a Cash Flow Event, the Company shall have the right to terminate this Agreement in its sole discretion.

(d) In the event that this Agreement shall be terminated pursuant to this Section 8.1, this Agreement shall be of no further force or effect and all further obligations of the parties under this Agreement (other than any obligations which specifically survive termination) shall be terminated without further liability of any party to the other; provided, however, that nothing herein shall relieve any party from liability for breach of any representation, warranty, covenant or agreement hereunder occurring prior to such termination. Nothing contained in this Agreement shall prevent any party from electing not to exercise any right it may have to terminate this Agreement and, instead, seeking any remedies, including equitable relief (including specific performance), to which it would otherwise be entitled in the event of breach of any other party hereto.

## 8.2. Notices

. All notices, requests, consents and other communications hereunder shall be in writing, shall be addressed to the receiving party's address set forth below or to such other address as a party may designate by notice hereunder, and shall be either (a) delivered by hand, (b) made by facsimile transmission, (c) sent by recognized overnight courier, or (iv) sent by certified mail, return receipt requested, postage prepaid. Any notice required to be given hereunder shall be sufficient if in writing and sent by email provided that this notice is also sent on the same day by reliable overnight delivery service (with proof of service), hand delivery or certified or registered mail (return receipt requested and first-class postage prepaid). All notices, demands, and other communications hereunder will not be deemed to have been duly given unless and until it is actually received by the intended recipient; provided, however, that notice given by electronic mail will be deemed to have been given when sent so long as no electronic notice is delivered to the sending party indicating that the electronic mail could not be delivered.

If to Purchaser or Merger Sub to:

8.2.1 (a): For any notice requests, consents and other communications related to Section 5.15

- Philipp von Hugo: philipp.hugo@qiagen.com
- Thierry Bernard: thierry.bernard@qiagen.com
- Axel Backheuer: axel.backheuer@qiagen.com
- Martin Potgeter: martin.potgeter@qiagen.com

8.2.1 (b) For any other requests, consents and other communications

Dr. Philipp von Hugo  
QIAGEN GmbH  
QIAGEN Strasse 1  
40724 Hilden  
Germany  
Telephone: 011 49 2103 29 11844  
Fax: 011 49 2103 29 21844

and

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.  
One Financial Center  
Boston, MA 02111  
Attn: Daniel H. Follansbee, Esq.  
Telephone: (617) 542-6000  
Fax: (617) 542-2241

If to the Company to:

NeuMoDx Molecular, Inc.  
1250 Eisenhower Place  
Ann Arbor, MI 48108  
Attn: Jeffrey S. Williams  
Email: [jeff@neumodx.com](mailto:jeff@neumodx.com)  
Telephone: (734) 527-0137

If to the Sellers' Representative and, after the Closing, to the Securityholders, to:

Shareholder Representative Services LLC  
950 17th Street, Suite 1400  
Denver, CO, 80202  
Attn: Managing Director  
Email: [deals@srsacquiom.com](mailto:deals@srsacquiom.com)  
Fax: (303) 623-0294  
Telephone: (303) 648-4085

With a copy (in the case of the Company or the Sellers' Representative), which shall not constitute notice to:

Jaffe, Raitt, Heuer & Weiss, P.C.  
27777 Franklin Road, Ste. 2500  
Southfield, MI 48034-8214  
Attn: Sara Kruse, Esq.  
Telephone: (248) 351-3000  
Fax: (248) 351-3082

All notices, requests, consents and other communications hereunder shall be deemed to have been given (a) if by hand, at the time of the delivery thereof to the receiving party at the address of such party set forth above, (b) if sent by facsimile transmission, at the time receipt has been acknowledged by electronic confirmation or otherwise, (c) if sent by overnight courier, on the next business day following the day such notice is delivered to the courier service, or (d) if sent by certified mail, on the 5<sup>th</sup> business day following the day such mailing is made.

8.3. Entire Agreement

. The Transaction Documents embody the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in the Transaction Documents shall affect, or be used to interpret, change or restrict, the express terms and provisions of this Agreement.

8.4. Binding Effect

. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors, heirs, personal representatives, legal representatives, and permitted assigns.

8.5. Assignment

. Neither this Agreement, nor any right hereunder, may be assigned by any of the parties hereto without the prior written consent of the other parties; provided, however, that Purchaser may assign all or part of its rights and obligations under this this Agreement to one or more direct or indirect Subsidiaries or Affiliate (in which event, representations and warranties relating to Purchaser shall be appropriately modified); provided that such assignment shall not relieve Purchaser from the performance of its obligations hereunder.

8.6. Modifications and Amendments

. The terms and provisions of this Agreement may be modified or amended only by written agreement executed by the Sellers' Representative, the Company and Purchaser.

8.7. Waivers and Consents

. The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions; provided that the Sellers' Representative is authorized to act after the Closing on behalf of the Sellers. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given and shall not constitute a continuing waiver or consent. No failure or delay by a party hereto in exercising any right, power or remedy under this Agreement, and no course of dealing between the parties hereto, shall operate as a waiver of any such right, power or remedy of the party. No single or partial exercise of any right, power or remedy under this Agreement by a party hereto, nor any abandonment or discontinuance of steps to enforce any such right, power or remedy, shall preclude such party from any other or further exercise thereof or the exercise of any other right, power or remedy hereunder. The election of any remedy by a party hereto shall not constitute a waiver of the right of such party to pursue other available remedies. No notice to or demand on a party not expressly required under this Agreement shall entitle the party receiving such notice or demand to any other or further notice or demand in similar or other circumstances or constitute a waiver of the rights of the party giving such notice or demand to any other or further action in any circumstances without such notice or demand.

#### 8.8. No Third Party Beneficiary

. Nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any Person other than the parties hereto and their respective heirs, personal representatives, legal representatives, successors and permitted assigns, any rights or remedies under or by reason of this Agreement.

#### 8.9. Severability

. If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any rule of law, or public policy, all other conditions and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner adverse to any party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in an acceptable manner to the end that transactions contemplated hereby are fulfilled to the extent possible.

#### 8.10. Publicity

. No party to this Agreement shall make, or cause to be made, any press release or public announcement in respect of this Agreement or the transactions contemplated hereby or otherwise communicate with any news media without the prior written consent of Purchaser and the Company, except as may be required by Law or the requirements of any national securities exchange or national automated quotation system, in which case the party proposing to issue such press release or make such public announcement shall use reasonable efforts to consult in good faith with the other party before issuing any such press release or making any such public announcement. The parties shall cooperate as to the timing and contents of any such press release



or public announcement. For the avoidance of doubt, any Seller that is a venture capital fund shall be permitted to disclose the terms of this Agreement to its limited partners and advisors; provided that such Seller notes that the terms of this Agreement and any related transactions are confidential.

#### 8.11. Governing Law

. This Agreement and the rights and obligations of the parties hereunder shall be construed in accordance with and governed by the Law of the State of Delaware without giving effect to the conflict of law principles thereof.

#### 8.12. Dispute Resolution

. Any dispute, difference or question arising between the parties in connection with this Agreement, the construction thereof, or the rights, duties or liabilities of either party shall be resolved by binding arbitration conducted in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association (the “AAA”) and otherwise as described in this Section 8.12. The arbitration shall be conducted by a panel of three (3) persons who are independent of all parties. Within thirty (30) days after initiation of arbitration, each of Purchaser and the Company (if prior to Closing) or the Sellers’ Representative (if after the Closing) shall select one person to act as arbitrator and the two party-selected arbitrators shall select a third arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the AAA. The place of arbitration shall be Wilmington, Delaware, and all proceedings and communications shall be in English. Either Purchaser or the Company (if prior to the Closing) or the Sellers’ Representative (if after the Closing) may apply to the arbitrators for interim injunctive relief until the arbitration decision is rendered or the dispute is otherwise resolved. Either Purchaser or the Company (if prior to Closing) or the Sellers’ Representative (if after the Closing) also may, without waiving any right or remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that party pending resolution of the dispute pursuant to this Section 8.12. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a party’s compensatory damages. Each of Purchaser and the Company (if prior to Closing) or the Sellers’ Representative (if after the Closing) shall bear its/their own costs and expenses, and the party that does not prevail in the arbitration proceeding shall pay the arbitrators’ fees and attorneys’ fees of the other party and any administrative fees of arbitration. Except to the extent necessary to confirm an award or decision or as may be required by applicable Law, neither a party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of Purchaser and the Company (if prior to Closing) or the Sellers’ Representative (if after the Closing). The arbitrators’ decision or award with respect to any dispute, difference or questions under this Section 8.12 shall be final and binding on the parties. The arbitrators shall issue a reasoned, written opinion with respect to any decision or award under this Section 8.12 and judgment on any such decision or award may be entered in any court of competent jurisdiction. From the date of submission of a dispute to arbitration pursuant to this Section 8.12, until such time as the dispute has become finally settled, the running of any time periods for fulfilling any obligations that are conditioned by the subject matter of the dispute shall become suspended.

8.13. Counterparts

. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same agreement.

8.14. Headings

. The descriptive headings contained in this Agreement are for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement.

8.15. Expenses

. Except as otherwise specified in this Agreement, all costs and expenses, including, without limitation, fees and disbursements of counsel, financial advisors and accountants, incurred in connection with this Agreement and the Transactions shall be paid by the party incurring such costs and expenses, whether or not any Closing shall have occurred.

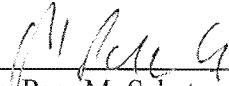
8.16. Further Assurances

. From and after the Closing Date, upon the request of either the Sellers' Representative or the Purchaser, each of the Parties hereto will use its commercially reasonable efforts to do, execute, acknowledge and deliver all such further acts, assurances, deeds, assignments, transfers, conveyances and other instruments and papers reasonably required or necessary to carry out the Transactions.

**[Remainder of page intentionally left blank.]**

IN WITNESS WHEREOF, the parties hereto have each executed and delivered this Agreement as of the day and year first above written.


QIAGEN NORTH AMERICAN HOLDINGS, INC.

By:   
Name: Peer M. Schatz  
Title: Chief Executive Officer

NEUMODX MOLECULAR, INC.

By: \_\_\_\_\_  
Name: Jeffrey S. Williams  
Title: Chief Executive Officer

NALEX MERGER SUB, INC.

By:   
Name: Peer M. Schatz  
Title: President

SELLERS' REPRESENTATIVE:

SHAREHOLDER REPRESENTATIVE SERVICES LLC, SOLELY IN  
ITS CAPACITY AS THE SELLERS' REPRESENTATIVE

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_


[Signature Page to Merger Agreement]

IN WITNESS WHEREOF, the parties hereto have each executed and delivered this Agreement as of the day and year first above written.

QIAGEN NORTH AMERICAN HOLDINGS, INC.

By: \_\_\_\_\_  
Name: Peer M. Schatz  
Title: Chief Executive Officer

NEUMODX MOLECULAR, INC.

By:  \_\_\_\_\_  
Name: Jeffrey S. Williams  
Title: Chief Executive Officer

NALEX MERGER SUB, INC.

By: \_\_\_\_\_  
Name: Peer M. Schatz  
Title: President

SELLERS' REPRESENTATIVE:

SHAREHOLDER REPRESENTATIVE SERVICES LLC, SOLELY IN  
ITS CAPACITY AS THE SELLERS' REPRESENTATIVE

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

[Signature Page to Merger Agreement]



IN WITNESS WHEREOF, the parties hereto have each executed and delivered this Agreement as of the day and year first above written.

QIAGEN NORTH AMERICAN HOLDINGS, INC.

By: \_\_\_\_\_  
Name: Peer M. Schatz  
Title: Chief Executive Officer

NEUMODX MOLECULAR, INC.


By: \_\_\_\_\_  
Name: Jeffrey S. Williams  
Title: Chief Executive Officer

NALEX MERGER SUB, INC.

By: \_\_\_\_\_  
Name: Peer M. Schatz  
Title: President

SELLERS' REPRESENTATIVE:

SHAREHOLDER REPRESENTATIVE SERVICES LLC, SOLELY IN  
ITS CAPACITY AS THE SELLERS' REPRESENTATIVE

By:  \_\_\_\_\_  
Name: Sam Riffe  
Title: Executive Director

[Signature Page to Merger Agreement]

## EXHIBITS AND SCHEDULES

## Schedule I

Regulatory availability dates of the Required Assays on N96 and N288

Test	Assay Design Initiated	System Integration Initiated	CE-IVD Submitted	CE-IVD Approved	FDA Submitted	FDA Cleared
Group B Strep	✓	✓	✓	✓	✓	✓
LDT (Open)	✓	✓	✓	✓	✓	✓
CT/NG	✓	✓	✓	✓	Apr-19	Q3 19
HBV Quant	✓	✓	✓	Nov-18	Q3 19	Q2 20
HCV Quant	✓	✓	Aug-18	Dec-18	Q3 19	Q2 20
CMV Quant	✓	✓	Oct-18	Dec-18	Q4 19	Q2 20
HIV Quant	✓	✓	Oct-18	Q1 19	Q3 19	Q2 20
Group A Strep	✓	✓	Dec-18	Dec-18	Q2 19	Q3 19
EBV	✓	Oct-18	Dec-18	Feb-19	N/A	N/A
Flu A, B & RSV	✓	Nov-18	Mar-19	Mar-19	Apr-19	Aug-19
Trichomonas	✓	✓	Dec-18	Dec-18	Apr-19	Q3 19

**Schedule II**Specification of the N96 and N288**System N288 and N96 Specifications**

The performance specifications of these systems will be measured using CT/NG as a model DNA assay and HCV as a model RNA assay. For the purpose of this specification list,

- N96 system including instrument, software and consumables shall be referred to as the "N96"
- N288 system including instrument, software and consumables shall be referred to as the "N288"
- N288 and N96 together shall be referred to as the "System"
- The "Cartridge" is the same for N96 and N288.
- The XCR module is the same for N96 and N288
- The control SW/FW of the XCR module is the same for N96 and N288
- Specifications shall be verified either by proof by design ("Design") and/or as proof by documentation ("Documentation")

#	Function	Parameter	Specification	Specs Verified by
	System components	Cartridges	N96 and N288 use the same Cartridge	Documentation
	System components	Instrument, cartridge, Software, accessories	All system components do not infringe any third party IP	Design
0	System components	Cost of goods	(i) Realization of production times and raw material costs of instrument, any consumables, spare parts or other components provided by company (with <169,000 USD as material costs for annual N288 instrument production between 26 and 75 units and <102,000 USD as material costs for annual N96 instrument production between 26 and 75 units) as a basis for cost calculations including implementation of already calculated cost reduction / process improvements.	Documentation

			<p>(ii) Company shall start replacing 3rd party enzymes &amp; probes with QIAGEN enzymes &amp; probes, to the extent possible without negatively impacting performance, into Company developed assays. Start immediately after signing</p> <p>(iii) Company shall support joint QIAGEN/Company design to cost phase in Q4 2018 with up to 20 per person workdays and 5 people. Goal of the design to cost phase is an agreed and prioritized list of COGS improvement projects by Q4 2018.</p> <p>(iv) Company shall start supporting top cost relevant projects (as per prioritized list according to (iii) above) with up to 20 workdays per person and 5 people,</p>	
1	<b>system compliance</b>	Device Master Record (DMR) and Design History File (DHF)	DMR and DHF Documentation compliant to 21CFR820 and ISO13485.	Document ation
2	<b>assay integration performance</b>	Throughput per shift	The N288 shall be able to process a minimum of 336 DNA samples to a result in 8 hours and 288 RNA samples to a result in 8 hours, the N96 144 DNA samples and 120 RNA samples	Document ation



3	<b>assay integration performance</b>	Meantime between repair	<p>System reliability shall be &gt;95% with a lower bound confidence interval of &gt;88%. Measured in number of successful runs from the number of total valid runs started.</p> <ul style="list-style-type: none"> <li>• A “run” is defined as a 8h operation period of the system, when processing at least 288 (for N288) and 96 (for N96) biological samples fully integrated.</li> <li>• “successful runs” are defined as follows: The System provides a plausible result for each test</li> <li>• “valid runs” are those that are counted in the verification campaign.</li> <li>• Requirements for campaign for each N96 and N288: min 3 instruments, min 40 valid runs (reasonably distributed across the instruments), min 2880 samples in total (10 tests per sample, tbd).</li> </ul>	Design
4	<b>Consumable interface</b>	Input Sample Tubes	<p>32 TUBE RACK: Tubes with OD 11x60 mm to 14x120mm.</p> <p>24 TUBE RACK: Tubes with OD 14.5x60 mm o 18x120mm</p>	Document ation
5	<b>Maintenance and Service</b>	Safety for Field Service	<ul style="list-style-type: none"> <li>- spare parts shall not weigh more than 15kg per component</li> <li>- service can be performed wearing laboratory gloves</li> <li>- common electrical safety standards (UL/CE) need to be applied to the design, where service access is required</li> <li>- no sharp edges shall endanger the FSE (injury and/or contamination).</li> </ul>	Document ation

6	<b>Maintenance and Service</b>	Serviceability without relocation	<p>-The System shall be serviceable (maintainable, repairable) without relocation.</p> <p>-Maintenance tasks (operator and FSE), frequently expected repairs and exchange of wear and tear parts shall be possible from the front with minimum distance to the back wall. If relocation for exceptional repairs cannot be avoided, a required distance of 0.7m to the back, 1.0m to the left side and 0.7m to the right side is acceptable, and the system shall be able to be moved without special equipment and the need for extensive recalibration</p>	Documentation
7	<b>operating conditions</b>	Instrument dimensions	Installed System dimensions, including the AutoLoader shelf, shall not exceed 2m x 1.10m x 2m (W x D x H) for the N288 and 1.37m x 1.09m x 1.08m (W x D x H) for the N96	Documentation
8	<b>system components</b>	Liquid transfer accuracy	The System shall pipette with maximum range tolerances of +/- 2 µl for a 20 µl aliquot, +/- 5uL for a 100 uL aliquot and +/- 25 µl for 500 µl aliquot.	Documentation
9	<b>system components</b>	XPCR Module, Thermocycling Module	The thermocycler, when operating in thermocycling conditions, shall have a temperature accuracy at the heater of +/- 1.0 °C with targets in the range of 50 - 65 °C (at the beginning of the hold time) and +/- 1.0 °C with targets in the range of 95 - 105 °C. (at the beginning of the hold time)	Design
10	<b>user experience</b>	Reachability of work table	The System design shall enable an operator with 625 mm arm length to reach all positions on the System required for primary operating functions (incl. cleaning) with the AutoLoader shelf removed or lowered.	Documentation
11	<b>user experience</b>	Sharp corners	There shall be no sharp corners on the System.	Documentation

12	<b>assay integration performance</b>	Time to first result	After sample loading, the System shall be able to deliver the first real-time PCR test results for DNA in <65 mins and RNA-targeting assays in <85 mins for routine testing, incl. required controls and calibrators.	Design
24	<b>assay integration performance</b>	Sample Process Control failure	SPC-1 and SPC-2 failure rates shall be calculated for CT/NG and HCV assays respectively. No more than 1% failure should be observed	Documentation
25	<b>Consumable interface</b>	Cartridge disposal	The Cartridge shall be compatible with standard biohazard waste disposal procedures following use on the System.	Documentation
26	<b>External Interfaces</b>	Power supply	The System shall be able to connect to a standard household socket for 20A 120V or 8A 230V (50 & 60 Hz respectively).	Documentation
27	<b>operating conditions</b>	Installation modularity	For installation the System must fit through doors with a clearance dimension of a minimum of 860 mm x 1985 mm (autoloader tray and touchscreen bezel can be dismantled)	Documentation
28	<b>operating conditions</b>	Environmental Conditions	The System shall perform according to specifications under climatic conditions 3K2, according to EN 60721-3-3:1995, but with * Low Air Temperature = 18°C * High Air Temperature = 26°C * Low Relative Humidity = 20% * High Relative Humidity = 60% (noncondensing) * Low Air Pressure = 77kPa. A separate climate study should prove system conformity for Low Air Temperature at 15°C and High Air Temperature at 28°C. For the avoidance of any doubt, no re-filing of the instrument for environmental testing is required.	Design
29				
30	<b>operating conditions</b>	Operation, electrical	90-264 VAC in frequency from 47 to 63 Hz (switched at factory or by service engineer)	Documentation

31	<b>operating conditions</b>	Cleaning tolerance	The System shall not degrade or be damaged beyond normal wear using deconex SOLARSEPT or equivalent decontamination solution.	Documentation
32	<b>system components</b>	Multiplex data acquisition	The System shall be able to acquire fluorescent signals from 1 to 5 different channels per assay at a defined stage of the assay profile.	Design
33	<b>system components</b>	Sample Processing, RLHS	Liquid handling robotic system shall have ability to dispense 5 µl to 1000 µl.	Documentation
34	<b>system components</b>	XPCR Module, Thermocycling Module	XPCR Module allows for independent thermal cycling across ALL 12 PCR chambers	Documentation
35	<b>system components</b>	XPCR Module, Thermocycling Module	The thermocycler shall control sample temperatures as measured in the PCR heater with targets in the range from 50 °C to 100 °C.	Design
35a	<b>System components</b>	XPCR Module	The XPCR module incl. control / FW /SW interfaces shall be integrate-able into the STAR Line of HAM robotics portfolio	Documentation
36	<b>system components</b>	XPCR Module, Thermocycling Module	The thermocycler, when operating in thermocycling conditions, shall have minimal thermal crosstalk from lanes that are being heated to lanes that are not being heated. Minimal is defined as crosstalk too low to significantly affect implementation of an independent thermocycling profile in neighboring lane, or should be compensated for by software.	Design
37	<b>system components</b>	XPCR, Optics Module	The spatial optical crosstalk between two adjacent lanes shall be less than or equal to <1%	Design
38	<b>system components</b>	XPCR, Optics Module	For FAM, HEX and ROX the spectral crosstalk shall be less than or equal to 10% uncompensated. For Cy5 and Cy5.5, the spectral crosstalk shall be less than or equal to 13% uncompensated.	Design



39	system components	XPCR, Optics Module	The RMS noise on dark signal of detector over instrument operating temperature range and instrument default measurement settings shall be less than or equal to 0.68% of full scale of detector output.	Documentation
40	system components	XPCR, Optics Module	The optical reading for any lane shall be less than or equal to 2% CV over 50 cycles with the fluorescence normalizer cartridge.	Design
41	system components	XPCR, Optics Module	The resolution of data acquisition shall be greater than or equal to 14 bits with accuracy better than 2 bits.	Documentation
42	system components	XPCR, Optics Module	Driving current for each individual LED can be adjusted by software with resolution of greater than 8 bits. The LED driving current shall be set to a value less than 80% of maximum allowable forward current for LED at time of production.  No LED binning should be required for any LED type in the XPCR module	Design
43	System Function	Monitor critical processing steps	The System shall be able to monitor critical process steps and act upon deviations with a defined error handling.	Documentation
44	System Function	US regulations	The System shall be compliant with relevant US regulations. Including: - "CSA C US" or "UL" label - electrical safety according to IEC 61010 - EMC compliance according to IEC 61326 - FCC label	Documentation
45	System Function	CE-IVD compliance	The System shall be compliant with 98/79/EC (In Vitro Diagnostic Medical Devices), including RoHS compliance	Documentation
46	System Function	Continuous Specimen Loading	System shall allow for continuous loading of specimen tube racks, up to a total of 9 racks, and have a	Documentation

			capacity to hold up to 288 specimen tubes in queue when using the 32-tube Hamilton specimen tube racks or 96 specimen for the N96 derivative system.	
47	<b>System Function</b>	Barcode readers	The System shall have barcode readers that can scan user, patient, and consumables and reagents information. The barcode reader shall have both 2D and linear barcode reading capability as needed to read the appropriate barcode.	Documentation
48	<b>System Function</b>	Random Access	Tubes of different specimen types (e.g. urine, serum, etc.) and specimens scheduled to receive different tests can be placed in a single specimen tube rack or multiple tube racks without regard to order or location of the various specimen tubes placed in the tube rack.	Documentation
49	<b>System Function</b>	Reagents & Consumables	All consumables and reagents are barcoded and the System tracks the type, quantity, expiry and remaining on-board shelf life, if required, for all consumables and reagents.	Documentation
50	<b>System Function</b>	Walk Away Window	Sufficient reagents and consumables can be stored in the System to conduct up to 288 tests, resulting in longer than 4 hours during which the operator does not need to interact with the System, for the N96 96 samples respectively	Documentation
51	<b>user experience</b>	No user interaction during processing	After assays have been assigned to loaded samples AND the System has been prepared with all required consumables for the respective tests AND the user has confirmed processing of the samples, the System shall be able to process the samples to reportable results without further user interaction.	Documentation

52	<b>user experience</b>	Amplification reagent cartridge on-board capacity	The System shall have a loading capacity for up to 30 PCR reagent strips (20 for N96).	Documentation
53	<b>user experience</b>	On-board storage of reagents	The System shall be able to support on-board storage of amplification reagents, extraction reagents and internal controls for a minimum of 10 days.	Documentation
54	<b>user experience</b>	CLIA moderate complexity prerequisites	The System shall be designed to obtain a moderate complexity rating according to CLIA categorization criteria, i.e. qualify for a score of 12 or less.	Documentation
55	<b>user experience</b>	Legibility of Graphical User Interface	The System's GUI shall be designed for legibility according to IEC 62366-1 and IEC 62366-2.	Documentation
56	<b>user experience</b>	Different user abilities and characteristics	The System shall provide safe conditions of use independent from users' abilities and characteristics.	Documentation
57	<b>user experience</b>	Software update	Software updates shall be achieved via a USB port	Documentation
58	<b>user experience</b>	Door lock	The service door cannot be opened by the user while the gantry is moving or is in an operational state.	Documentation
59	<b>user experience</b>	Covers	Sheet metal or plastic covers shall be in place over all mechanical and electrical components as necessary to protect user from moving parts, heat or live electrical parts.	Documentation
61	<b>assay integration performance</b>	Waste capacity	The System shall provide a capacity for liquid and solid waste sufficient for processing 288 samples or more for N288 and 96 samples or more for N96	Documentation
62	<b>data analysis</b>	Analyze PCR raw data	The System shall be able to analyze PCR raw data according to assay specific, predefined analysis parameters, provided in an assay specific file format linked to the analyze SW in a flexible way that future assay specific parameter or analysis files can be added on same SW System	Documentation
63	<b>External Interfaces</b>	Connection to laboratory infrastructure	The System shall be operable when externally connected only to an	Documentation

			uninterruptable power supply and - optionally - to an Ethernet cable.	
64	<b>operating conditions</b>	Wall placement	The operation of the System shall require a distance to the back wall of not more than 10 cm.	Documentation
65	<b>operating conditions</b>	Maximum Weight of instrument	The System shall have a maximum weight of <250 kg/sqm.	Design
66	<b>system components</b>	Application Process Files: concept	The System shall be able to process samples to test results according to pre-defined application process files, which contain all relevant parameters to execute the complete process correctly without further user input after initiation of the process.	Design
67	<b>system components</b>	Sample input volume	The System shall support assay specific extraction process input volumes ranging from 0.025 -1.0 ml when using full parallelism of the XCR cartridge (12) or, with a future software change, input volume ranging from 0.025 – 2.0 ml when using 50% of the XCR cartridge (6).	Documentation
68	<b>System Function</b>	Chain of Custody	The System shall track relevant sample and process related data during the complete process from data acquisition to the final report. This includes especially sample IDs and position information, assay assignments, reagent types, lot numbers, expiration dates, run information (times, temperatures, steps, operators), process deviations (events which differ from the expected and validated routine workflow, such as pauses, errors, re-tries, non-standard user interactions etc.) & error flags.	Documentation
69	<b>System Function</b>	Random Access function	The System shall be able to process single samples and smaller groups of samples, without the need to batch multiple samples of the same type or the same assay assignment.	Design

70	<b>System Function</b>	Inventory Management	The System shall provide an inventory management function, which constantly keeps track of all loaded materials and provides inventory information to the user. The processing time for inventory mgmt. – if required at all and not shadowed during physical workflow operation – shall not exceed more than 2% of workflow processing time.	Documentation
71	<b>user experience</b>	Continuous loading of samples	The System shall provide the operator with the ability to load and define samples continuously before, after, and during processing of other samples, up to a defined capacity	Design
72	<b>user experience</b>	Manual entry of sample ID	If no sample ID was acquired from the sample tube, the System shall provide the user with the ability to enter or scan IDs manually.	Design
73	<b>user experience</b>	Managing continuous loading of consumables	Loading consumables shall not lead to interruption of running processes.	Documentation
74	<b>user experience</b>	Manual assay assignment	The System shall provide the operator with an efficient option to manually assign tests to pending samples.	Documentation
75	<b>user experience</b>	Ease of Use	The System shall be operable effectively and safely by personnel with basic training and knowledge of laboratory automation and/or molecular biology methods.	Documentation
76	<b>user experience</b>	Prevent incorrect loading	The design of consumables shall prevent wrong loading of the items onto the System, including orientation of parts and interchangeability of parts (in case correct positioning order is critical)	Design
78	<b>Miscellaneous</b>	Poison Plasma	The absence of significant inhibition, caused by the effects of “poison plasma” shall be demonstrated with <1% UNR results from plasma samples sourced from a minimum of 3 suppliers.	Documentation

79	<b>data analysis</b>	Extendable software architecture	The software architecture shall enable the assay developer to add new assay specific data analysis functionality without impacting existing software/assays.	Documentation
80	<b>user experience</b>	Handling of invalid results	<p>The System shall report results, which have been flagged as invalid during the process, without any calculated value.</p> <p>Remark: Samples shall still be included in the report, but no analysis result shall be included. Samples shall be clearly marked as invalid, and the report shall contain a clear description of the error, which has occurred during processing.</p>	Documentation
81	<b>user experience</b>	Interface Accessories	The System shall be compatible with a standard computer keyboard, mouse (2-button), and USB color printer, although the primary interface is the touchscreen.	Documentation
82	<b>assay integration performance</b>	Rate of successful sample processing	<p>The System shall be able to process 98% of all samples to technically correct results, under the condition that samples are provided as specified (i.e. correct material, sufficient quality, validated tube format, requested volume). Not more than 1% of all samples shall be lost during processing.</p> <p>Remark: This means, that 50% of errors do not lead to loss of sample and can be re-run. Error rates include failures of instrument, software, disposables and generic chemistry. Assay-specific effects</p>	Design



			have to be added (including expected rate of "bad" clinical material).	
83	<b>System Function</b>	Walk Away Window	The System can operate without an operator present until the System: 1) processes all samples for which a valid test requisition exists; 2) exhausts the required consumable or reagent in least abundance; or 3) the waste bin or both waste bottles reach capacity.	Design
84	<b>user experience</b>	Effective monitoring	The design shall allow support for the user in effectively monitoring the System during operation. Remark: for example, a concept for remote notification of any kind (email, PCR tool, smartphone etc.); and audio alerts to get user's attention within the lab.	Document ation
85	<b>assay integration performance</b>	Routine hands-on time	The System shall provide the operator with the ability to perform all required pre-analytical interaction, reagent preparation and loading, sample loading, in-process interaction, and post-analytical interaction for up to 288 samples in less than 20 minutes.	Document ation
86	<b>Consumable interface</b>	Cartridge	The System shall perform the following operations in the Cartridge – Transfer $\geq 94\%$ of liquid from Capture Plate to XPCR Cartridge, capture $\geq 90\%$ of magnetic particles from liquid,	Design

			perform washing of captured magnetic particles, expose captured magnetic particles to elution solution, and elute NA from magnetic particles	
87	Consumable interface	Cartridge	Cartridge enables 1 to 12 simultaneous extraction processes	Documentation
88	Consumable interface	PCR Cartridge	Allow accurate positioning of reaction mixture in the reactor using a volume of $19 \pm 2$ microliters of reaction mixture	Design
89	Consumable interface	Capture Plate	24 well microplate containing dried extraction reagents; each well has a maximum volume of $\sim 1.5$ mL	Documentation
90	Consumable interface	Capture Plate	Well format mates with heater module to provide thermal contact	Documentation
91	Consumable interface	Buffer Trough	Each trough contains one of the four types of Sample preparation buffers	Documentation
92	Consumable interface	Buffer Trough	$\sim 80$ mL of Sample preparation buffer will be sealed into each trough	Documentation
93	Consumable interface	XPCR Cartridge, Capture Plate, Buffer Plates	All consumables shall be assembled in a controlled environment setting isolated from laboratory areas	Documentation
94	Consumable interface	Barcode content	Barcodes on consumables and reagents will contain the information necessary to initiate System performance.	Documentation
95	Consumable interface	Specimen Rack loading	1 to 9 specimen tube racks may be prepared and loaded onto the System at any time for N288 and 1 to 3 specimen tube racks for N96	Design
96	data analysis	Support quantitative analysis	The System shall be able to perform an automated analysis for quantitative assays.	Documentation
97	data analysis	Support qualitative analysis	The System shall be able to perform an automated analysis for qualitative assays.	Documentation
98	data analysis	Validity of Curves	The System shall check validity of amplification curves of samples, controls and calibrators for anomalies and act according to assay specific, predefined rules.	Documentation

99	<b>data analysis</b>	Support "Calibration Run" concept	The System shall support assays that reuse reagent-specific standard curves for quantitation.	Documentation
100	<b>data analysis</b>	Support "Internal Control - Quantitation Standard" Concept	The System shall, support assays that use individual IC amplification curves for quantitation, based on assay specific and predefined calibration data.	Documentation
101	<b>data analysis</b>	Automated calibration management	The System shall be able to manage calibration data for different assays according to predefined validity criteria, without requiring user decisions on validity or preference of individual calibration data sets.	Documentation
102	<b>External Interfaces</b>	UPS	If connected to a defined UPS solution, the System shall be able to complete running PCR analyses and perform a controlled shutdown of other running processes, if power is not restored within a defined time limit. The System will not start processing new samples during a UPS-bridged power loss phase.	Documentation
103	<b>External Interfaces</b>	LIMS interface	The System shall allow a bi-directional LIMS interface. The architecture and specifications are HL7 compliant	Documentation
104	<b>External Interfaces</b>	Support development of LDT assays	The System shall provide a customer application developer with the ability to define the automated process for LDT assays, including sample preparation, controls & calibrators, amplification reaction setup, PCR cycling, data analysis and reporting, within defined limits.	Documentation
105	<b>Maintenance and Service</b>	Pre-defined error handling	The System shall be able to act on a defined list of errors with pre-defined error handling routines.	Documentation
106	<b>Maintenance and Service</b>	Remote servicing	The System should be designed to include a remote servicing functionality in the future.	Documentation

107	<b>Maintenance and Service</b>	Effective extended troubleshooting	The System shall provide service personnel with the ability to perform extended troubleshooting effectively, including exchange of parts or modules.  Preliminary software tools for diagnosis and analysis shall be available. Upgraded versions will be developed after Launch.	Documentation
108	<b>Maintenance and Service</b>	Software Update	The System shall provide the customer with the ability to perform an update of the software without the presence of an FSE.	Documentation
109	<b>Maintenance and Service</b>	Preventive Maintenance	The System shall require not more than two preventative maintenance per year.	Design
110	<b>Maintenance and Service</b>	Logging usage	The System shall log usage of lifetime-critical hardware components. The instrument shall enable the field service engineer to analyze these usage statistics in the future.	Documentation
111	<b>operating conditions</b>	Field calibration	The instrument can be mechanically calibrated (XYZ axes) in the field by a trained technician with special tools and fixtures.	Documentation
112	<b>system components</b>	Sample Processing, RLHS	System shall perform the operations of transferring sample from specimen tubes to Capture Plate, transfer of processed sample from Capture Plate to Cartridge, transfer of eluted NA from Cartridge to Assay Strip and transfer of reaction ready mix from Assay Strip back to Cartridge for amplification and detection	Documentation
113	<b>system components</b>	Capture Plate	The System shall perform the following operations in the Capture Plate - reconstitution of Capture Plate reagents, target lysis, and binding of NA to coated magnetic particles using assay specific protocols (ADFs).	Design

114	system components	Loading checks	The System will check for correct loading of the specimen tubes, relative to the work list automatically at the beginning of the run. System will prompt the user in case of an error/mismatch.	Design
115	system components	Capture Plate	The Capture Plate module shall be able to maintain a target temperature in the range of 37 to 80 °C with precision of +/- 3 °C (when measured at 60°C with 1000µL volume). Each Capture Plate well temperature shall be independently controllable	Design
116	system components	XPCR Modules	N288 contains four XPCR Modules capable of processing samples in a Cartridge through NA extraction, amplification and detection; 2 modules for a N96 system.	Documentation
117	system components	XPCR Module	XPCR Module applies sufficient and appropriately distributed pressure on Cartridge to enable fluidic pathways to function as necessary to implement the process flow on the Cartridge	Design
118	system components	XPCR Module	XPCR Module ensures thermal contact between RELEASE heating module and Cartridge.	Documentation
119	system components	XPCR Module	XPCR Module ensures thermal contact between PCR heater assembly and Cartridge.	Design
120	system components	XPCR Module, Magnetic Flux Generator	Magnetic flux generated is sufficient to provide capture >90% of magnetic particles in the Cartridge	Documentation
121	system components	XPCR Module, Valving Mechanism	Valving mechanism provides a sequence of operations capable of implementing the assay workflow with high-fidelity	Documentation
122	system components	XPCR Module, Valving Mechanism	Valving mechanism ensures that less than 10% of liquid is lost during the RELEASE heating step	Documentation
123	system components	XPCR Module, Valving Mechanism	Valving mechanism ensures that less than 10% of liquid is lost during the PCR thermocycling step	Documentation

124	system components	XPCR Module, Syringe Pump Module	Syringe Pump Module enables the delivery of desired WASH volumes (100-1000 uL) to each lane with a tolerance of $\pm 10$ uL	Documentation
125	system components	XPCR Module, Syringe Pump Module	Syringe Pump Module enables the reproducible delivery of AIR volume to displace the WASH liquid over the bead chamber prior to the delivery of RELEASE liquid	Documentation
126	system components	XPCR Module, Syringe Pump Module	Syringe Pump Module enables the delivery of desired ELUTE volume (nominal 19uL) from each lane with a tolerance of $\pm 1.5$ uL	Documentation
127	system components	XPCR Module, Syringe Pump Module	Syringe Pump Module enables the reproducible aspiration of programmed ELUTE volume from each lane with a failure rate not to exceed 1% (i.e. less than 1 failed lane across 8X Cartridges )	Documentation
128	system components	XPCR Module, Release Heating Module	Release Heating Module ensures uniform temperature across the bead chamber region and supports the achievement of desired LoD for model assays	Documentation
129	system components	XPCR Module, Release Heating Module	Release Heating Module ensures the adequate denaturation of any leftover Proteinase K enzyme so as not to adversely affect downstream PCR/RTPCR	Documentation
130	system components	XPCR Module, Release Heating Module	Release Heating Module ensures a temperature of 75-85 deg C with a tolerance of $\pm 2$ deg C measured at the heater	Design
131	system components	XPCR Module, Thermocycling Module	The maximum undershoot of sample temperature as measured in the PCR chamber fluid below the target in thermocycling mode shall be 1.0 °C for targets in the range of 50 °C to 65 °C . The maximum overshoot at 95°C shall be 1.0 °C.	Documentation
132	system components	XPCR, Optics Module	Each optical channel within each lane shall be read within +/- 2 seconds of the specified time within the overall thermal cycle profile, for all cycles in the overall thermal cycle profile, for all lanes in a	Design



			cartridge that could be running different thermal cycle profiles.	
133	system components	XPCR, Optics Module	The total time for scanning all 12 chambers in a cartridge, data acquisition, and processing for all fluorescence channels shall be less than 8 seconds	Documentation
134	System Function	Random Access efficiency	Even for single samples, the System shall run with the highest efficiency with regard to throughput and cost per sample (with the exception of <10mL of wash and/or release buffer for priming). The System shall not waste reagents for unused processing positions.	Documentation
135	System Function	Support future assays	The System shall be able to support future assays with similar workflows to existing assays	Documentation
136	System Function	Control Frequency	If one set of controls is processed per up to 24h for each assay, the System shall be technically able to deliver reliable sample results for the same period	Documentation
137	System Function	Redundant consumables	The System shall be able to deplete individual disposables and reagents, and continue the process with new consumable if available in the instrument, without the need for user interaction.	Documentation
138	System Function	Operation, Process Checks, Built in Tests	Verification of program to be executed within the System shall be conducted as part of Initialization routines at startup of instrument. These INIT routines shall test & verify optical paths, mechanical movements & thermal cycling of heating elements. Failure of any INIT Test shall result in the instrument reporting this to the user including status that identifies the failed test/component.	Design

139	<b>System Function</b>	Automatic Start	Once the necessary type and quantity of reagents and consumables are loaded onto the System, along with at least one specimen tube with an associated test requisition, the System automatically accesses the specimen tube and necessary consumables and reagents to begin processing the sample.	Design
140	<b>user experience</b>	Continuous loading of consumables	The System shall provide the operator with the ability to load and unload (if required) disposables, extraction reagents and amplification reagents continuously with a maximum waiting time of 3 minutes during the majority of the routine operation.	Documentation
141	<b>user experience</b>	Automatic assay assignment	If the System is connected to a LIMS (directly or via middleware) AND the operator has loaded appropriately barcoded samples, the System shall be able to assign the correct assays to the loaded samples without user interaction.	Design
142	<b>user experience</b>	Review and confirm assignments	If configured by an administrator, the System shall provide the user with the ability to review and confirm assay assignments to samples before processing.	Design
143	<b>user experience</b>	Validate prerequisites before processing	Directly after assay assignment and before processing samples, the System shall validate the prerequisites to process the loaded samples with the planned assays to results without human intervention. If this validation fails, the respective samples shall not be processed, until the error has been resolved.	Design
144	<b>user experience</b>	Result management	The System shall provide a result management and archiving functionality, also considering the use of multiple Systems in the same laboratory.	Documentation

145	<b>user experience</b>	Support maintenance tasks	The System shall support the user in execution of maintenance tasks by guidance and automated processes.	Documentation
146	<b>user experience</b>	Global settings	The System shall provide an administrator with the ability to configure global settings of the System, such as default settings to reduce/standardize workflow complexity for the operator, define local network settings, or otherwise adapt the System behavior to the local infrastructure and workflows, within defined limits.	Documentation
147	<b>user experience</b>	Internationalization	The System shall support different language localizations of the GUI and output files	Documentation
148	<b>user experience</b>	Sample Processing, Sample Accessioning Capability	System shall accept specimen data entry through manual single handed scanning with a barcode wand, touchscreen or an auxiliary USB keyboard.	Design
149	<b>user experience</b>	Worklist setup	Software will guide a user through the process of setting up a run and correctly loading the System.	Design
150	<b>assay integration performance</b>	Inventory scan time	The System shall be able to recognize all consumables up to the specified maximum capacity within 10 minutes.	Design
151	<b>assay integration performance</b>	Daily Maintenance hands-on time	The hands-on time for daily maintenance of the System shall be less than 10 minutes per day, excluding time for automated maintenance processes.	Documentation
152	<b>assay integration performance</b>	Start-up time	After switching it on, the System shall be operational within 10 minutes.	Documentation
153	<b>data analysis</b>	Check rules	The System shall be able to check for individual targets (i.e. individual optical channels) of each sample, control and calibrator compliance to a set of assay specific, predefined validity rules.	Design
154	<b>External Interfaces</b>	Support 1D sample barcodes	The System shall be able to automatically acquire sample IDs from 1D barcode formats.	Documentation

			Minimum requirement: Code 39, Code 128 and subtypes, Codabar.	
155	<b>External Interfaces</b>	Protect application process files against manipulation	The System shall provide the application developer with the ability to protect application process files against manipulation.	Design
156	<b>Installation</b>	Installation Time	Installation of the System shall be possible for one FSE within 1 working day (8 hours).	Documentation
157	<b>Maintenance and Service</b>	Error tolerance	If an error can be confined to a distinct module of the System, processes on parallel and on downstream modules of the System shall not be stopped, unless defined otherwise in a specific error handling.	Design
158	<b>Maintenance and Service</b>	Audit Trail	The System shall track all process relevant user interactions and system processes in a protected audit trail, which is accessible by an administrator.	Documentation
159	<b>System Function</b>	STAT samples	The System shall provide the operator with the ability to load high priority samples, which will be processed in the next available slot, without interrupting running processes. Unloading of queued samples for routine testing shall be avoided.	Design
160	<b>System Function</b>	Support Laboratory-Developed Tests	The System shall provide the user with the ability to process lab-developed and user-validated assays	Documentation
161	<b>System Function</b>	QC before patient results	The System shall ensure that all required QC procedures related to a specific sample and assay (such as Full Process Control or Calibrator runs) have been completed, before routine results can be obtained and approved by a user. This should not exclude parallel processing of samples and controls, but control results need to be evaluated first.	Design

162	System Function	Support Full Process Controls	The System shall support assay specific external controls, which are treated the same way as routine samples during processing	Documentation
163	System Function	Handle partially used disposables	If the system workflow requires the operator to take off partially used disposables, e.g. for cleaning purposes, the System shall be able to recognize the exact amount of partially used disposable parts after re-loading.	Design
164	System Function	Multiple assay assignments to one sample	The System shall be able to handle multiple assay assignments to the same sample.	Design
165	user experience	Sample type information	The System shall be able to acquire and manage sample type information during the complete process.	Documentation
166	user experience	Continuous loading of external controls and calibrators	The System shall provide the user with the ability to continuously load external controls and calibrators, the same way as defined for samples	Design
167	user experience	Flexibility of consumables loading	The System shall provide the user with the ability to load disposables, extraction reagents and amplification reagents in any order.	Documentation
168	user experience	Definable stability time	The System shall be able to manage specific stability times for sample prep and amplification reagents.	Design
169	user experience	Review and approval of results	The System shall provide a user with approver rights with the ability to review and approve results, in combination with accompanying data, before results are exported to LIMS or a result report is generated.	Documentation
170	user experience	Restrict access to moving or hazardous parts	The System shall control operator access to the worktable of the instrument and grant access only if no processes are running on the worktable.	Design
171	user experience	Operability by one person	The System shall enable a single operator to operate the complete workflow with the maximal throughput.	Documentation

172	<b>user experience</b>	Administration environment	The System shall provide an administration environment, which includes functions that are restricted to users with administration rights.	Documentation
173	<b>user experience</b>	User management	The System shall provide a password protected user management system.	Documentation
174	<b>user experience</b>	Management of Application Process Files	The System shall provide an administrator with the ability to manage application process files for different assays. This includes addition of new applications, updates of existing applications and deletion or inactivation of obsolete applications.	Documentation
175	<b>user experience</b>	User Training	A training shall enable the intended users to operate the primary operating functions of the System according to the intended use.	Documentation
176	<b>system components</b>	XPCR, Optics Module	The raw optical signal variation between lanes shall be such that the minimum signal is greater than 50% of the maximum signal.	Documentation



**Schedule III****Assay Specifications**

Assay specification Blood borne viruses (HBV, HCV, HIV)

	SPECIFICATION		
PARAMETER	HBV	HCV	HIV-1
Intended use	Monitor	Monitor (& Screening optional)	Monitor & Screening
FDA Guidance documents			ucm080790
Compliance	DMR and DHF Documentation compliant to 21CFR820 and ISO13485.		
CLSI	follow all relevant guidelines		
Input Vol from Primary tube	1.0mL		
Input Vol from Secondary tube	650uL		
Matrix	Plasma and serum		Plasma
Targets	no spec		Dual target assay with targets in non-drug resistant region
Inclusivity	HBV genotypes A, B, C, D, E, F, G, and H	HCV genotypes 1a, 1b, 2,3,4,5,6	Group M (subtypes A, B, C, D, F, G, CRF01_AE, CRF02_AG Group N and Group O
Limit of Detection (all strains)	≤6IU/mL	≤10 IU/mL	≤20 cop/mL
LLoQ	HCV and HBV LLoQ ≤ 10 IU; HIV ≤ 20 cp/mL		
Linear range	LOD to 9.0 log10 IU/mL	LOD to 8.0 log10 IU/mL	LOD to 7.0 log10 cop/mL
Precision (inter assay)	< 0.25 log IU/mL		
Accuracy	± 0.3 log IU/mL		
Reproducibility	< 0.3 log IU/mL		

<b>Cross-reactivity</b>	<p>Greater than or equal to the following concentrations: Hepatitis A virus 100,000 PFU/mL  Hepatitis B virus 100,000 IU/mL  Hepatitis C virus 100,000 IU/mL  Herpes simplex virus 1 (HSV-1) 100,000 PFU/mL  Herpes simplex virus 2 (HSV-2) 75,000 PFU/mL  Human herpes virus 6 100,000 copies/mL  Human herpes virus 8 42,000 PFU/mL  HIV-2 5,500 PFU/mL  Human T-cell lymphotropic virus (HTLV) 100,000 vp/mL  West Nile virus 100,000 copies/mL  Parvovirus B19 100,000 IU/mL  Cytomegalovirus 100,000 copies/mL  Epstein-Barr virus 100,000 copies/mL  Adenovirus type 5 100,000 PFU/mL  Dengue virus 100,000 copies/mL  Influenza A virus 100,000 PFU/mL  Staphylococcus aureus 1,000,000 CFU/mL  Propionibacterium acnes 1,000,000 CFU/mL  Staphylococcus epidermidis 1,000,000 CFU/mL  Neisseria gonorrhoeae 1,000,000 CFU/mL  Chlamydia trachomatis 300,000 IFU/mL  Candida albicans 1,000,000 CFU/mL</p>
<b>Interfering agents</b>	<p>Endogenous:  albumin (90 mg/mL), hemoglobin (5 mg/mL), triglycerides (30 mg/mL), or unconjugated bilirubin (0.2 mg/mL)</p>

<b>Interfering agents</b>	<p>Exogenous:</p> <p>Lopinavir, indinavir, saquinavir, ritonavir, nelfinavir mesylate, darunavir, amprenavir, atazanavir</p> <p>Nevirapine, efavirenz, rilpivirine, clarithromycin, amphotericin B</p> <p>Tenofovir disoproxil fumarate, adefovir dipivoxil, ribavirin, enfuvirtide, maraviroc, raltegravir, dolutegravir</p> <p>Abacavir sulfate, didanosine, zidovudine, lamivudine, stavudine, entecavir, telbivudine, emtricitabine</p> <p>Paroxetine HCl, fluoxetine, sertraline 6 Ganciclovir, valacyclovir, acyclovir, rifampin/rifampicin, ethambutol</p> <p>Ciprofloxacin, azithromycin, amoxicillin, cephalixin, ampicillin, trimethoprim</p> <p>Valganciclovir hydrochloride, boceprevir, telaprevir, simeprevir, sofosbuvir</p> <p>Pegylated interferon alpha -2b, interferon alpha -2a, interferon alpha -2b</p> <p>Heparin, EDTA, sodium citrate</p> <p>Tipranavir</p> <p>Isoniazid</p>
<b>Clinical Specimens Tested for Interference</b>	<p>Antinuclear antibody (ANA)</p> <p>Systemic lupus erythematosus (SLE)</p> <p>Rheumatoid factor (RF)</p> <p>Hyperglobulinemia Alcoholic cirrhosis (AC)</p> <p>Rheumatoid arthritis (RA)</p> <p>Alcoholic hepatitis Anti-Jo1 antibody (JO-1)</p> <p>Non-alcoholic hepatitis Multiple myeloma (MM)</p> <p>Autoimmune hepatitis Hemolyzed (elevated hemoglobin)</p> <p>Elevated alanine aminotransferase (ALT)</p> <p>Icteric (elevated bilirubin)</p> <p>Hepatocellular carcinoma (HCC)</p> <p>Lipemic (elevated lipid)</p> <p>Multiple sclerosis (MS)</p> <p>Elevated protein</p>
<b>System Failure Rate</b>	IND rate of $\leq 1\%$ (The assay shall successfully process $\geq 99\%$ of clinical samples in claimed sample types)
<b>controls failure rate</b>	UNR rate of $\leq 1\%$ (the control failure rate should be $<1\%$ )
<b>Cross contamination</b>	0% cross contamination demonstrated below titers of $1E9$ IU/mL (HBV)
<b>Kit stability</b>	Min. 12 months accelerated and min. 6 months real time at launch with goal of ultimately reaching 24 months real time data
<b>IP</b>	Assays do not infringe any third party IP
<b>Onboard open kit stability</b>	30 days

<b>Control concept</b>	Full process Positive, Negative and internal controls (ready to use and trackable) – incorporating encapsulated nucleic acid		
<b>Calibration</b>	Full process calibrators (encapsulated nucleic acid) Stored calibration curves Traceable to current WHO standard used for calibration		
<b>TAT</b>	<85 minutes		
<b>Clinical Sensitivity</b>	100 % (with samples >100 cop/mL samples)	100 % (with samples >150 cop/mL samples)	100 % (with samples >200 cop/mL samples)
<b>Clinical Specificity</b>	100% (excluding samples within 0.5log LLoQ)		
<b>Method correlation</b>	within $\pm 0.5 \log_{10}$ IU/ml within the defined quantitation range and at the medical decision points and $\pm 0.5 \log_{10}$ IU/ml per genotype within the defined quantitation range		
<b>Guard-banding &amp; robustness</b>	According to EU CTS	According to EU CTS	According to EU CTS
<b>COGS</b>	COGS shall be equal or lower than defined in Schedule IV below		

## Assay specifications CTNG

	<b>SPECIFICATION</b>
<b>PARAMETER</b>	<b>CT/NG</b>
<b>Intended use</b>	Screening (symptomatic and asymptomatic)
<b>FDA Guidance documents</b>	21CFR866.3120 - Chlamydia serological reagents 21CFR866.3390 - Neisseria spp. direct serological test reagents 21CFR862.2570 - Instrumentation for clinical multiplex test systems
<b>Compliance</b>	DMR and DHF Documentation compliant to 21CFR820 and ISO13485.
<b>CLSI</b>	follow all relevant guidelines
<b>Input Vol from Primary tube</b>	1.5mL (urine) tbd (Swab) 1.0mL (PreservCyt)
<b>Input Vol from Secondary tube</b>	550uL
<b>Matrix</b>	URINE - F&M  ENDO SWAB in UTM/UVT/M4
<b>Targets</b>	CT dual target (Genome and cryptic plasmid) NG single gene with multiple copies

<b>Inclusivity</b>	• CT serovars (A, B, Ba, C, D, E, F, G, H, I, Ia, J, K, L1, L2, L2b, L3, nvCT)
	• NG (20 strains)
<b>Limit of Detection ( all strains)</b>	• CT: 30 EB/mL for swabs
	• NG: <10 cfu/mL for swabs
	• CT: <10 EB/mL for urine
	• NG: <5 cfu/mL for urine
	80% or more of the CT serovars shall be <50EB/ml and the remaining CT serovars shall be <100 EB/ml
<b>Reproducibility</b>	Moderate pos (5x-10x LOD) 100% positive rate Low pos (2x-4x LOD) ≥99% positive rate Negative ≥99% negative rate
<b>Format</b>	CT/NG test shall be multiplexed and require only one xPCR lane for processing
<b>Reporting</b>	Report for CT & NG

<b>Analytical Specificity</b>	<p> <i>Achromobacter xerosis</i> <i>Helicobacter pylori</i> <i>Neisseria sicca</i> <i>Acinetobacter calcoaceticus</i> Hepatitis B virus (HBV) <i>Neisseria subflava</i> <i>Acinetobacter lwoffii</i> Hepatitis C virus (HCV) <i>Neisseria subflava</i> 6458 <i>Acinetobacter</i> sp. genospecies 3 Human immunodeficiency virus <i>Neisseria subflava</i> 6617 <i>Actinomyces israelii</i> Human papillomavirus type 16 (CaSki cells) <i>Neisseria subflava</i> 6618 <i>Actinomyces pyogenes</i> Human papillomavirus type 18 (HeLa cells) <i>Neisseria subflava</i> 7441 Adenovirus Herpes Simplex Virus (HSV-1) <i>Neisseria subflava</i> 7452 <i>Aerococcus viridans</i> Herpes Simplex Virus (HSV-2) <i>Neisseria weaverii</i> <i>Aeromonas hydrophila</i> <i>Kingella denitrificans</i> <i>Pantoea agglomerans</i> <i>Alcaligenes faecalis</i> <i>Kingella kingae</i> <i>Paracoccus denitrificans</i> <i>Bacillus subtilis</i> <i>Klebsiella oxytoca</i> <i>Pasteurella maltocida</i> <i>Bacillus thuringiensis</i> <i>Klebsiella pneumoniae</i> ss ozaenae <i>Pediococcus acidilactica</i> <i>Bacteroides caccae</i> <i>Lactobacillus acidophilus</i> <i>Peptostreptococcus anaerobius</i> <i>Bacteroides fragilis</i> <i>Lactobacillus brevis</i> <i>Peptostreptococcus asacharolyticus</i> <i>Bacteroides ureolyticus</i> <i>Lactobacillus crispatus</i> <i>Peptostreptococcus magnus</i> <i>Bifidobacterium adolescentis</i> <i>Lactobacillus delbrueckii</i> subsp. <i>lactis</i> <i>Plesiomonas shigelloides</i> <i>Bifidobacterium breve</i> <i>Lactobacillus jensenii</i> <i>Prevotella bivia</i> <i>Bifidobacterium longum</i> <i>Lactobacillus lactis</i> <i>Prevotella corporis</i> <i>Branhamella catarrhalis</i> <i>Lactobacillus oris</i> <i>Prevotella intermedia</i> <i>Brevibacterium linens</i> <i>Lactobacillus parabuchneri</i> <i>Propionibacterium acnes</i> <i>Campylobacter gracilis</i> <i>Lactobacillus vaginalis</i> <i>Proteus mirabilis</i> <i>Campylobacter jejuni</i> <i>Lactococcus lactis cremoris</i> <i>Proteus vulgaris</i> <i>Candida albicans</i> <i>Legionella bozemni</i> <i>Providencia stuartii</i> <i>Candida glabrata</i> <i>Legionella pneumophila</i> <i>Pseudomonas aeruginosa</i> <i>Candida guilliermondii</i> <i>Listeria monocytogenes</i> <i>Pseudomonas fluorescens</i> <i>Candida krusei</i> <i>Micrococcus luteus</i> <i>Pseudomonas putida</i> <i>Candida parapsilosis</i> <i>Mobiluncus curtisii</i> subsp. <i>curtisii</i> <i>Rahnella aquatilis</i> <i>Candida tropicalis</i> <i>Mobiluncus curtisii</i> subsp. <i>holmesii</i> <i>Rhizobium radiobacter</i> <i>Chlamydomyces pneumoniae</i> <i>Mobiluncus mulieris</i> <i>Rhodospirillum rubrum</i> <i>Chromobacter violaceum</i> <i>Moraxella catarrhalis</i> <i>Ruminococcus productus</i> <i>Chryseobacterium meningosepticum</i> <i>Moraxella lacunata</i> <i>Saccharomyces cerevisiae</i> <i>Citrobacter braakii</i> <i>Moraxella osloensis</i> <i>Salmonella Choleraesuis</i> <i>Citrobacter freundii</i> <i>Morganella morganii</i> <i>Salmonella Minnesota</i> <i>Clostridium innocuum</i> <i>Mycobacterium avium</i> <i>Salmonella typhimurium</i> <i>Clostridium perfringens</i> <i>Mycobacterium gordonae</i> <i>Serratia denitrificans</i> <i>Clostridium sporogenes</i> <i>Mycobacterium smegmatis</i> <i>Serratia marcescens</i> <i>Corynebacterium genitalium</i> <i>Mycoplasma genitalium</i> <i>Staphylococcus aureus</i> <i>Corynebacterium renale</i> <i>Mycoplasma hominis</i> <i>Staphylococcus epidermidis</i> <i>Corynebacterium xerosis</i> <i>Mycoplasma pneumoniae</i> <i>Staphylococcus saprophyticus</i> <i>Cryptococcus neoformans</i> <i>Neisseria cinerea</i> 832 <i>Streptococcus agalactiae</i> <i>Cytomegalovirus</i> <i>Neisseria cinerea</i> 3306 <i>Streptococcus anginosus</i> </p>
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	Deinococcus radiodurans Neisseria cinerea 3307 Streptococcus bovis
	Deinococcus radiopugnans Neisseria cinerea 3308 Streptococcus
	dysgalactiae
	Derxia gummosa Neisseria cinerea 6317 Streptococcus equinis
	Edwardsiella tarda Neisseria dentrificans Streptococcus mitis
	Eikenella corrodens Neisseria elongata subsp.
	niroreducans Streptococcus mutans
	Enterobacter aerogenes Neisseria flava Streptococcus pneumoniae
	Enterobacter cloacae Neisseria flavescens Streptococcus pyogenes
	Enterococcus avium Neisseria kochi Streptococcus salivarius
	Enterococcus faecalis Neisseria lactamica Streptococcus sanguis
	Enterococcus faecium Neisseria meningitidis 135 Streptomyces griseinus
	Epstein Barr Virus Neisseria meningitidis Serogroup
	A
	Treponema pallidum
	Erwinia herbicola Neisseria meningitidis Serogroup
	B
	Trichomonas vaginalis
	Erysipelothrix rhusiopathiae Neisseria meningitidis Serogroup
	C
	Ureaplasma urealyticum
	Escherichia coli Neisseria meningitidis Serogroup
	D
	Veillonella parvula
	Ewingella americana Neisseria meningitides Serogroup
	Y
	Vibrio parahaemolyticus
	Flavobacterium
	meningosepticum Neisseria mucosa Weissella paramesenteroides
	Fusobacterium nucleatum Neisseria perflava 837 Yersinia enterocolitica
	Gardnerella vaginalis Neisseria perflava 911
	Gemella haemolysans Neisseria perflava 6339
	Gemella morbillorum Neisseria perflava 6340"

<b>Interfering agents</b>	<b>Swab Exogenous (such brands or any other band with identical active compound)</b>  Blood Mucin Seminal Fluid Hormones (Progesterone, Beta Estradio LGV II (CT EB) Vagisil Anti Itch Cream Clotrimazole Vaginal cream Preparation H Hemorrhoidal cream Miconazole 3 Monistat 1 Zovirax Cold Sore Cream Vagisil Moisturizer Vagi Gard Moisturizing Gel KY Jelly Personal Lubricant Yeast Gard Douche Delfen Vaginal Contraceptive Foam VH Essentials Povidone-Iodine Medicated Douche Leukocytes
	<b>Urine Exogenous (such brands or any other band with identical active compound)</b>  Blood Mucin Seminal Fluid Hormones (Progesterone/Beta Estradiol) LGV (CT EB) Leukocytes Norforms Deodorant Suppositories BSA Glucose Bilirubin Aspirin Azithromycin Doxycycline Organisms - UTI Candida albicans/ Staphylococcus atireus/Escherichia coli Acetaminophen Vagisil Feminine Powder Acidic Urine Alkaline Urine

<b>Competitive Inhibition</b>	No inhibition from >3 moieties tested If inhibition exists... do a dose response to characterize lowest level with no inhibition.
<b>System Failure Rate</b>	IND rate of $\leq 1\%$ (The assay shall successfully process $\geq 99\%$ of clinical samples in claimed sample types)
<b>Controls Failure rate</b>	UNR rate of $\leq 1\%$ (the control failure rate should be $<1\%$ )
<b>Cross contamination</b>	0% run to run sample to sample $<1\%$ concentration TBD
<b>Kit stability</b>	12 months real time at Closing
<b>Transport stability for kits</b>	Specimen stability 2-30°C 60 days. At -20°C to -70°C up to six months
<b>IP</b>	Assays do not infringe any third party IP
<b>Onboard open kit stability</b>	30 days
<b>Control concept</b>	Current SPC1 will be used as process control. Recommend external controls include Acrometrix CTNG control
<b>TAT</b>	$<65$ minutes
<b>Clinical Sensitivity &amp; Specificity</b>	Sensitivity $>95\%$ Specificity $>99\%$ negative predictive value $> 99\%$
<b>COGS</b>	COGS shall be equal or lower than defined in Schedule IV below

Assay specifications CMV:

	<b>SPECIFICATION</b>
<b>PARAMETER</b>	<b>CMV</b>
<b>Intended use</b>	<b>Monitor</b>
<b>FDA Guidance documents</b>	n/a
<b>Compliance</b>	DMR and DHF Documentation compliant to 21CFR820 and ISO13485.
<b>CLSI</b>	follow all relevant guidelines
<b>Input Vol from Primary tube</b>	1.0mL
<b>Input Vol from Secondary tube</b>	350uL Plasma 250uL whole blood

<b>Matrix</b>	Plasma only
<b>Targets</b>	no specification
<b>Inclusivity</b>	gB-1, gB-2, gB-3 and gB-4 and all drug resistant targets
<b>Limit of Detection (all strains)</b>	$\leq 50$ IU/mL
<b>LLoQ</b>	LOD
<b>Upper Limit</b>	$\geq 1.0E07$ IU/mL
<b>Precision (inter assay)</b>	$< 0.25$ log IU/mL
<b>Accuracy</b>	$\pm 0.3$ log IU/mL
<b>Reproducibility</b>	$< 0.3$ log IU/mL
<b>Cross-reactivity</b>	<p><b>Viruses</b></p> <p>Adenovirus type 5</p> <p>BK Polyomavirus</p> <p>Epstein-Barr Virus</p> <p>Hepatitis B Virus</p> <p>Hepatitis C Virus</p> <p>Herpes Simplex Virus type 2</p> <p>Herpes Simplex Virus type 1</p> <p>Human Herpes Virus type-6</p> <p>Human Herpes Virus type-7</p> <p>Human Herpes Virus type-8</p> <p>Human Immunodeficiency Virus-1</p> <p>Human Immunodeficiency Virus-2</p> <p>Human Papillomavirus</p> <p>JC virus</p> <p>Parvovirus B19</p> <p>Varicella-Zoster Virus</p> <p><b>Bacteria</b></p> <p>Chlamydia trachomatis</p> <p>Clostridium perfringens</p> <p>Enterococcus faecalis</p> <p>Escherichia coli</p> <p>Klebsiella pneumonia</p> <p>Listeria monocytogenes</p> <p>Mycobacterium avium</p> <p>Mycoplasma pneumonia</p> <p>Neisseria gonorrhoeae</p> <p>Propionibacterium acnes</p> <p>Salmonella typhimurium</p> <p>Staphylococcus aureus</p> <p>Staphylococcus epidermidis</p> <p>Streptococcus pneumonia</p> <p>Streptococcus pyogenes</p>

	<b>Yeast&amp;Fungi</b> Aspergillus niger Candida albicans Cryptococcus neoformans
<b>Interfering agents</b>	triglycerides (34.5 g/L) conjugated bilirubin (0.25 g/L) unconjugated bilirubin (0.25 g/L) albumin (58.7 g/L) hemoglobin (2.9 g/L) human DNA (2 mg/L)
	Antibimicrobial Cefotetan; Clavulanate potassium; Fluconazole; Piperacillin; Tazobactam sodium; Sulfamethoxazole; Ticarcillin disodium; Trimethoprim; Vancomycin; Compounds for Treatment of Herpes Viruses Ganciclovir; Valganciclovir; Cidofovir; Foscarnet; Immune Suppressant Azathioprine; Cyclosporine; Everolimus; Mycophenolate mofetil; Mycophenolic acid; Prednisone; Sirolimus; Tacrolimus;
<b>Clinical Specimens Tested for Interference</b>	systemic lupus erythematosus rheumatoid arthritis antinuclear antibody
<b>System Failure Rate</b>	IND rate of $\leq 1\%$ (The assay shall successfully process $\geq 99\%$ of clinical samples in claimed sample types)
<b>Controls Failure rate</b>	UNR rate of $\leq 1\%$ (the control failure rate should be $<1\%$ )
<b>Cross contamination</b>	0% at $\geq 1.0E6$ IU/mL
<b>Kit stability</b>	12 months real time at Closing
<b>IP</b>	Assays do not infringe any third party IP
<b>Onboard open kit stability</b>	30 days
<b>Control concept</b>	• Full process Positive (High +ve & Low +ve) and internal controls (ready to use and trackable) – incorporating encapsulated nucleic acid
<b>Calibration</b>	Full process calibrators (encapsulated nucleic acid) Stored calibration curves Current WHO standard used for calibration
<b>TAT</b>	<65 minutes

<b>Clinical Sensitivity &amp; Specificity</b>	Sensitivity >99% Specificity >99%; excluding samples with 0,5 log LLOQ
<b>Method correlation</b>	No difference shall be observed between an existing IVD-marked quantitative real-time PCR kit(s) for detection assay when testing clinical patient samples. Specifically, the criteria are as follows: <ul style="list-style-type: none"> <li>• Passing-Bablok intercept between -0.3 log10 and 0.3 log10</li> <li>• Passing-Bablok slope between 0.95 and 1.05</li> </ul>
<b>COGS</b>	COGS shall be equal or lower than defined in Schedule IV below

## Assay specifications EBV

	<b>SPECIFICATION</b>
<b>PARAMETER</b>	<b>EBV</b>
<b>Intended use</b>	<b>Monitor</b>
<b>FDA Guidance documents</b>	<b>n/a; assay will only be CE Marked and NOT PMA</b>
<b>Compliance</b>	DMR and DHF Documentation compliant to 21CFR820 and ISO13485.
<b>CLSI</b>	follow all relevant guidelines
<b>Input Vol from Primary tube</b>	1.0mL
<b>Input Vol from Secondary tube</b>	350uL Plasma 250uL whole blood
<b>Matrix</b>	Plasma and whole blood
<b>Targets</b>	no specification
<b>Inclusivity</b>	no specification
<b>Limit of Detection (all strains)</b>	<60 IU/mL (WHO standard)
<b>LLoQ</b>	LOD
<b>Linear range</b>	$\geq 1.0E07$ IU/mL to LOD
<b>Precision (inter assay)</b>	< 0.25 log IU/mL
<b>Accuracy</b>	$\pm 0.3$ log IU/mL
<b>Reproducibility</b>	< 0.3 log IU/mL



<b>Cross-reactivity</b>	<p><b>Viruses</b></p> <p>Adenovirus type 5  BK Polyomavirus  Epstein-Barr Virus  Hepatitis B Virus  Hepatitis C Virus  Herpes Simplex Virus type 2  Herpes Simplex Virus type 1  Human Herpes Virus type-6  Human Herpes Virus type-7  Human Herpes Virus type-8  Human Immunodeficiency Virus-1  Human Immunodeficiency Virus-2  Human Papillomavirus  JC virus  Parvovirus B19  Varicella-Zoster Virus</p> <p><b>Bacteria</b></p> <p>Chlamydia trachomatis  Clostridium perfringens  Enterococcus faecalis  Escherichia coli  Klebsiella pneumonia  Listeria monocytogenes  Mycobacterium avium  Mycoplasma pneumonia  Neisseria gonorrhoeae  Propionibacterium acnes  Salmonella typhimurium  Staphylococcus aureus  Staphylococcus epidermidis  Streptococcus pneumonia  Streptococcus pyogenes</p> <p><b>Yeast&amp;Fungi</b></p> <p>Aspergillus niger  Candida albicans  Cryptococcus neoformans</p>
<b>Interfering agents</b>	<p>triglycerides (34.5 g/L)  conjugated bilirubin (0.25 g/L)  unconjugated bilirubin (0.25 g/L)  albumin (58.7 g/L)  hemoglobin (2.9 g/L)  human DNA (2 mg/L)</p>

	Antibimicrobial Cefotetan; Clavulanate potassium; Fluconazole; Piperacillin; Tazobactam sodium; Sulfamethoxazole; Ticarcillin disodium; Trimethoprim; Vancomycin; Compounds for Treatment of Herpes Viruses Ganciclovir; Valganciclovir; Cidofovir; Foscarnet; Immune Suppressant Azathioprine; Cyclosporine; Everolimus; Mycophenolate mofetil; Mycophenolic acid; Prednisone; Sirolimus; Tacrolimus;
<b>Clinical Specimens Tested for Interference</b>	systemic lupus erythematosus rheumatoid arthritis antinuclear antibody
<b>System Failure Rate</b>	IND rate of $\leq 1\%$ (The assay shall successfully process $\geq 99\%$ of clinical samples in claimed sample types)
<b>Controls Failure rate</b>	UNR rate of $\leq 1\%$ (the control failure rate should be $<1\%$ )
<b>Cross contamination</b>	0% at $\geq 1.0E6$ IU/mL
<b>Kit stability</b>	12 months real time at Closing
<b>IP</b>	Assays do not infringe any third party IP
<b>Onboard open kit stability</b>	30 days
<b>Control concept</b>	<ul style="list-style-type: none"> <li>• Full process Positive (High +ve &amp; Low +ve) and NEG internal controls (ready to use and trackable) – incorporating encapsulated nucleic acid</li> </ul>
<b>Calibration</b>	Full process calibrators (encapsulated nucleic acid) Stored calibration curves Current WHO standard used for calibration
<b>TAT</b>	$<65$ minutes
<b>Clinical Sensitivity &amp; Specificity</b>	Sensitivity $>95\%$
<b>Method correlation</b>	No difference shall be observed between an existing IVD-marked quantitative real-time PCR kit(s) for detection assay when testing clinical patient samples. Specifically, the criteria are as follows: <ul style="list-style-type: none"> <li>• Passing-Bablok intercept between <math>-0.3 \log_{10}</math> and <math>0.3 \log_{10}</math></li> <li>• Passing-Bablok slope between 0.95 and 1.05</li> </ul>
<b>COGS</b>	COGS shall be equal or lower than defined in Schedule IV below

## Assay specifications Flu A/B &amp; RSV

	SPECIFICATION
<b>PARAMETER</b>	<b>Flu A/B/RSV</b>
<b>Intended use</b>	<b>Screening</b>
<b>FDA Guidance documents</b>	<b>21CFR862.2570 - Instrumentation for clinical multiplex test systems</b> <b>21CFR866.3980 Respiratory viral panel multiplex nucleic acid assay.</b>
<b>Compliance</b>	DMR and DHF Documentation compliant to 21CFR820 and ISO13485.
<b>CLSI</b>	follow all relevant guidelines
<b>Input Vol from Primary tube</b>	1.5mL (Swab) 3.0mL (uTM)
<b>Input Vol from Secondary tube</b>	550uL
<b>Matrix</b>	1. nasopharyngeal swab 2. Nasal Swabs 3. UTM
<b>Targets</b>	no specification
<b>Inclusivity</b>	All Influenza A, B
	RSV A & B
<b>Limit of Detection ( all strains)</b>	Flu A $\leq 1E-1.0$ TCID <sub>50</sub> /mL Flu B $\leq 1E$ TCID <sub>50</sub> /mL
	Flu A: <1 TCID <sub>50</sub> /mL (MODEL STRAIN). Flu B: < TCID <sub>50</sub> /mL (MODEL STRAIN) RSV: < 2 TCID <sub>50</sub> /mL (MODEL STRAIN) hMPV: < 2 TCID <sub>50</sub> /mL (MODEL STRAIN)
	RSV $\leq 2E0.0$ TCID <sub>50</sub> /mL
<b>Reproducibility</b>	Moderate pos (5x-10x LOD) 100% positive rate Low pos (2x-4x LOD) $\geq 99\%$ positive rate Negative $\geq 99\%$ negative rate
<b>Format</b>	Multiplexed and require only one xPCR lane for processing
<b>Reporting</b>	Report for all

<b>Analytical Specificity</b>	<p>"Viruses</p> <p>Adenovirus type 5</p> <p>BK Polyomavirus</p> <p>Epstein-Barr Virus</p> <p>Hepatitis B Virus</p> <p>Hepatitis C Virus</p> <p>Herpes Simplex Virus type 2</p> <p>Herpes Simplex Virus type 1</p> <p>Human Herpes Virus type-6</p> <p>Human Herpes Virus type-7</p> <p>Human Herpes Virus type-8</p> <p>Human Immunodeficiency Virus-1</p> <p>Human Immunodeficiency Virus-2</p> <p>Human Papillomavirus</p> <p>JC virus</p> <p>Parvovirus B19</p> <p>Varicella-Zoster Virus</p> <p>Bacteria</p> <p>Chlamydia trachomatis</p> <p>Clostridium perfringens</p> <p>Enterococcus faecalis</p> <p>Escherichia coli</p> <p>Klebsiella pneumonia</p> <p>Listeria monocytogenes</p> <p>Mycobacterium avium</p> <p>Mycoplasma pneumonia</p> <p>Neisseria gonorrhoeae</p> <p>Propionibacterium acnes</p> <p>Salmonella typhimurium</p> <p>Staphylococcus aureus</p> <p>Staphylococcus epidermidis</p> <p>Streptococcus pneumonia</p> <p>Streptococcus pyogenes</p> <p>Yeast&amp;Fungi</p> <p>Aspergillus niger</p> <p>Candida albicans</p> <p>Cryptococcus neoformans</p>
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<b>Interfering agents</b>	<b>Endogenous</b> Purified mucin protein Human blood <b>Nasal sprays or drops</b> Phenylephrine Oxymetazoline Saline/Sodium chloride Albuterol <b>Nasal corticosteroids</b> Beconase AQ Beclomethasone Dexamethasone Flunisolide Triamcinolone Budesonide Mometasone Fluticasone <b>Nasal gel</b> Luffa operculata, Galphimia, Glaucia, Histaminum hydrochloricum, Sulfur <b>Throat lozenges</b> Benzocaine Menthol <b>Anti-viral drugs</b> Zanamivir Oseltamivir Ribavirin <b>Antibiotic, nasal ointment</b> Mupirocin <b>Antibiotic, systemic</b> Tobramycin
<b>Competitive Inhibition</b>	no competitive inhibition in all sample matrices
<b>System Failure Rate</b>	The assay shall successfully process $\geq 99\%$ of clinical samples in claimed sample types
<b>Controls Failure rate</b>	the control failure rate should be $<1\%$
<b>Cross contamination</b>	0% run to run sample to sample $<0.5\%$ concentration 10000X LOD
<b>Kit stability</b>	12 months real time at Closing
<b>Transport stability</b>	Specimen stability 2-30°C 60 days. At -20°C to -70°C up to six months
<b>IP</b>	Assays do not infringe any third party IP
<b>Onboard open kit stability</b>	30 days
<b>Control concept</b>	• Full process Positive (+ve FluA,B,RSV, HMPV) and negative plus internal controls (ready to use and trackable) – incorporating encapsulated nucleic acid

<b>Calibration</b>	Full process calibrators (encapsulated nucleic acid) Stored calibration curves
<b>TAT</b>	<85 minutes
<b>Clinical Sensitivity &amp; Specificity</b>	Sensitivity >98% Specificity >98% negative predictive value > 99%
<b>COGS</b>	COGS shall be equal or lower than defined in Schedule IV below

Assay specifications: *Trichomonas vaginalis*

	<b>SPECIFICATION</b>
<b>PARAMETER</b>	<b><i>Trichomonas vaginalis</i></b>
<b>Intended use</b>	<b>Screening (symptomatic and asymptomatic)</b>
<b>FDA Guidance documents</b>	<b>21CFR866.3860 <i>Trichomonas vaginalis</i> nucleic acid assay</b>
<b>Compliance</b>	DMR and DHF Documentation compliant to 21CFR820 and ISO13485.
<b>CLSI</b>	follow all relevant guidelines
<b>Input Vol from Primary tube</b>	1.5mL (Swab) 1.0mL (eNAT) 3ml (UMT)
<b>Input Vol from Secondary tube</b>	550uL
<b>Matrix</b>	1. transport media (utm and eNAT) 2. Endocervical swabs 3. Vaginal Swabs 4. Urine
<b>Targets</b>	DNA
<b>Inclusivity</b>	include Drug resistant strains (QIAGEN to support, but cost paid by NeuMoDx)
<b>Limit of Detection ( all strains)</b>	< 2.5 trichomonads/mL
<b>Reproducibility</b>	Moderate pos (5x-10x LOD) 100% positive rate Low pos (2x-4x LOD) ≥99% positive rate Negative ≥99% negative rate
<b>Format</b>	Multiplexed and require only one xPCR lane for processing



<b>Analytical Specificity</b>	<p> <i>Achromobacter xerosis</i> <i>Helicobacter pylori</i> <i>Neisseria sicca</i>  <i>Acinetobacter calcoaceticus</i> Hepatitis B virus (HBV) <i>Neisseria subflava</i> <i>Acinetobacter lwoffii</i> Hepatitis C virus (HCV)  <i>Neisseria subflava</i> 6458 <i>Acinetobacter</i> sp. genospecies 3  Human immunodeficiency virus <i>Neisseria subflava</i> 6617  <i>Actinomyces israelii</i> Human papillomavirus type 16 (CaSki cells) <i>Neisseria subflava</i> 6618 <i>Actinomyces pyogenes</i> Human papillomavirus type 18 (HeLa cells) <i>Neisseria subflava</i> 7441  Adenovirus Herpes Simplex Virus (HSV-1) <i>Neisseria subflava</i> 7452 <i>Aerococcus viridans</i> Herpes Simplex Virus (HSV-2)  <i>Neisseria weaverii</i> <i>Aeromonas hydrophila</i> <i>Kingella denitrificans</i>  <i>Pantoea agglomerans</i> <i>Alcaligenes faecalis</i> <i>Kingella kingae</i>  <i>Paracoccus denitrificans</i> <i>Bacillus subtilis</i> <i>Klebsiella oxytoca</i>  <i>Pasteurella maltocida</i> <i>Bacillus thuringiensis</i> <i>Klebsiella pneumoniae</i> ss <i>ozaenae</i> <i>Pediococcus acidilactica</i> <i>Bacteroides caccae</i> <i>Lactobacillus acidophilus</i> <i>Peptostreptococcus anaerobius</i> <i>Bacteroides fragilis</i> <i>Lactobacillus brevis</i>  <i>Peptostreptococcus asacharolyticus</i> <i>Bacteroides ureolyticus</i>  <i>Lactobacillus crispatus</i> <i>Peptostreptococcus magnus</i>  <i>Bifidobacterium adolescentis</i> <i>Lactobacillus delbrueckii</i> subsp. <i>lactis</i> <i>Plesiomonas shigelloides</i> <i>Bifidobacterium breve</i>  <i>Lactobacillus jensenii</i> <i>Prevotella bivia</i> <i>Bifidobacterium longum</i>  <i>Lactobacillus lactis</i> <i>Prevotella corporis</i> <i>Branhamella catarrhalis</i>  <i>Lactobacillus oris</i> <i>Prevotella intermedia</i> <i>Brevibacterium linens</i>  <i>Lactobacillus parabuchneri</i> <i>Propionibacterium acnes</i>  <i>Campylobacter gracilis</i> <i>Lactobacillus vaginalis</i> <i>Proteus mirabilis</i> <i>Campylobacter jejuni</i> <i>Lactococcus lactis cremoris</i>  <i>Proteus vulgaris</i> <i>Candida albicans</i> <i>Legionella bozemannii</i>  <i>Providencia stuartii</i> <i>Candida glabrata</i> <i>Legionella pneumophila</i>  <i>Pseudomonas aeruginosa</i> <i>Candida guilliermondii</i> <i>Listeria monocytogenes</i> <i>Pseudomonas fluorescens</i> <i>Candida krusei</i>  <i>Micrococcus luteus</i> <i>Pseudomonas putida</i>  <i>Candida parapsilosis</i> <i>Mobiluncus curtisii</i> subsp. <i>curtisii</i>  <i>Rahnella aquatilis</i>  <i>Candida tropicalis</i> <i>Mobiluncus curtisii</i> subsp. <i>holmesii</i> <i>Rhizobium radiobacter</i>  <i>Chlamydomyces pneumoniae</i> <i>Mobiluncus mulieris</i>  <i>Rhodospirillum rubrum</i>  <i>Chromobacter violaceum</i> <i>Moraxella catarrhalis</i> <i>Ruminococcus productus</i>  <i>Chryseobacterium meningosepticum</i> <i>Moraxella lacunata</i> <i>Saccharomyces cerevisiae</i>  <i>Citrobacter braakii</i> <i>Moraxella osloensis</i> <i>Salmonella</i>  <i>Choleraesuis</i>  <i>Citrobacter freundii</i> <i>Morganella morganii</i> <i>Salmonella</i>  Minnesota </p>
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	<p> <i>Clostridium innocuum</i> <i>Mycobacterium avium</i> <i>Salmonella typhimurium</i>  <i>Clostridium perfringens</i> <i>Mycobacterium gordonae</i> <i>Serratia denitrificans</i>  <i>Clostridium sporogenes</i> <i>Mycobacterium smegmatis</i> <i>Serratia marcescens</i>  <i>Corynebacterium genitalium</i> <i>Mycoplasma genitalium</i>  <i>Staphylococcus aureus</i>  <i>Corynebacterium renale</i> <i>Mycoplasma hominis</i> <i>Staphylococcus epidermidis</i>  <i>Corynebacterium xerosis</i> <i>Mycoplasma pneumoniae</i>  <i>Staphylococcus saprophyticus</i>  <i>Cryptococcus neoformans</i> <i>Neisseria cinerea</i> 832 <i>Streptococcus agalactiae</i>  <i>Cytomegalovirus</i> <i>Neisseria cinerea</i> 3306 <i>Streptococcus anginosus</i>  <i>Deinococcus radiodurans</i> <i>Neisseria cinerea</i> 3307 <i>Streptococcus bovis</i>  <i>Deinococcus radiopugnans</i> <i>Neisseria cinerea</i> 3308  <i>Streptococcus dysgalactiae</i>  <i>Derxia gummosa</i> <i>Neisseria cinerea</i> 6317 <i>Streptococcus equinus</i>  <i>Edwardsiella tarda</i> <i>Neisseria dentrificans</i> <i>Streptococcus mitis</i>  <i>Eikenella corrodens</i> <i>Neisseria elongata</i> subsp.  <i>niroreducans</i> <i>Streptococcus mutans</i>  <i>Enterobacter aerogenes</i> <i>Neisseria flava</i> <i>Streptococcus pneumoniae</i>  <i>Enterobacter cloacae</i> <i>Neisseria flavescens</i> <i>Streptococcus pyogenes</i>  <i>Enterococcus avium</i> <i>Neisseria kochi</i> <i>Streptococcus salivarius</i>  <i>Enterococcus faecalis</i> <i>Neisseria lactamica</i> <i>Streptococcus sanguis</i>  <i>Enterococcus faecium</i> <i>Neisseria meningitidis</i> 135 <i>Streptomyces griseinus</i>  <i>Epstein Barr Virus</i> <i>Neisseria meningitidis</i> Serogroup A  <i>Treponema pallidum</i>  <i>Erwinia herbicola</i> <i>Neisseria meningitidis</i> Serogroup B  <i>Trichomonas vaginalis</i>  <i>Erysipelothrix rhusiopathiae</i> <i>Neisseria meningitidis</i> Serogroup C  <i>Ureaplasma urealyticum</i>  <i>Escherichia coli</i> <i>Neisseria meningitidis</i> Serogroup D  <i>Veillonella parvula</i>  <i>Ewingella americana</i> <i>Neisseria meningitides</i> Serogroup </p>
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	Y Vibrio parahaemolyticus Flavobacterium meningosepticum Neisseria mucosa Weissella paramesenteroides Fusobacterium nucleatum Neisseria perflava 837 Yersinia enterocolitica Gardnerella vaginalis Neisseria perflava 911 Gemella haemolysans Neisseria perflava 6339 Gemella morbillorum Neisseria perflava 6340"
<b>Interfering agents</b>	personal lubricants, personal deodorants, spermicides, anti-fungals, intravaginal hormones, gastric mucus, seminal fluid, whole blood, Glacial Acetic Acid
<b>System Failure Rate</b>	The assay shall successfully process $\geq 99\%$ of clinical samples in claimed sample types
<b>Controls Failure rate</b>	the control failure rate should be $< 1\%$
<b>Cross contamination</b>	0% run to run sample to sample $< 0.5\%$ concentration 10000X LOD
<b>Kit stability</b>	6 months real time at Closing and 12 months accelerated
<b>Transport stability</b>	Specimen stability 2-8°C 8 days and 30°C 48hrs
<b>IP</b>	Assays do not infringe any third party IP
<b>Onboard open kit stability</b>	30 days
<b>Control concept</b>	• Full process Positive and negative plus internal controls (ready to use and trackable) – incorporating encapsulated nucleic acid
<b>TAT</b>	$< 65$ minutes
<b>Clinical Sensitivity &amp; Specificity</b>	Sensitivity $> 98\%$ Specificity $> 98\%$ negative predictive value $> 99\%$
<b>COGS</b>	COGS shall be equal or lower than defined in Schedule IV below

Assay specifications GBS:

PARAMETER	SPECIFICATION
<b>Intended use</b>	Screening (symptomatic and asymptomatic)
<b>FDA Guidance documents</b>	21 CFR 866.3740 Streptococcal spp. serological reagents 21 CFR 862.2570 - Instrumentation for clinical multiplex test systems

<b>Compliance</b>	DMR and DHF Documentation compliant to 21CFR820 and ISO13485.
<b>CLSI</b>	follow all relevant guidelines
<b>Matrix</b>	Lim Broth enriched vaginal/rectal swab for US and CE-IVD Direct Swab (COPAN in Amies & Dual rayon swab) for CE-IVD and FDA claim available in Q2 2020
<b>Input Vol from Primary tube</b>	1 ml
<b>Targets</b>	Not defined
<b>Inclusivity</b>	Serotypes Ia, Ib, Ic, II, III, IV, IVc, V, VI, VII, VIII and IX plus Non-hemolytic
<b>Analytical sensitivity / Limit of Detection</b>	<1000 CFU/mL
<b>detects across this range</b>	1.0+E03 - 1.0+E09 CFU/mL; no quantitative assay
<b>Reproducibility</b>	reproducibility as described in the 510k document

<b>Analytical Specificity</b>	<p> <i>Abiotrophia defectiva</i>  <i>Acinetobacter baumannii</i>  <i>Actinobacillus pleuropneumoniae</i>  <i>Aeromonas hydrophila</i>  <i>Anaerococcus lactolyticus</i>  <i>Anaerococcus prevotii</i>  <i>Anaerococcus tetradius</i>  <i>Arcanobacterium pyogenes</i>  <i>Bacillus cereus</i>  <i>Bacteroides fragilis</i>  <i>Bifidobacterium brevis</i>  <i>Bordetella pertussis</i>  <i>Bulkholderia cepacia</i>  <i>Candida albicans</i>  <i>Candida glabrata</i>  <i>Candida tropicalis</i>  <i>Citrobacter freundii</i>  <i>Clostridium difficile</i>  <i>Corynebacterium urealyticum</i>  <i>Enterobacter aerogenes</i>  <i>Enterobacter cloacae</i>  <i>Enterococcus durans</i>  <i>Enterococcus faecalis</i>  <i>Enterococcus faecium</i>  <i>Enterococcus gallinarum</i>  <i>Escherichia coli</i>  <i>Finergold magna</i>  <i>Fusobacterium nucleatum</i>  <i>Gardnerella vaginalis</i>  <i>Haemophilus influenzae</i>  <i>Hafnia alvei</i>  Human DNA  Human DNA  <i>Klebsiella oxytoca</i>  <i>Lactobacillus acidophilus</i>  <i>Lactobacillus casei</i>  <i>Lactobacillus delbrueckii lactis</i>  <i>Lactobacillus gasseri</i>  <i>Lactobacillus plantarum</i>  <i>Lactobacillus spp (CAP strain)</i>  <i>Listeria monocytogenes</i>  <i>Micrococcus luteus</i>  <i>Moraxella atlantae</i>  <i>Moraxella catarrhalis</i>  <i>Morganella morganii</i>  <i>Neisseria gonorrhoeae</i> </p>
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	<p>Pantoea agglomerans Pasteurella aerogenes Peptinophilus assacharolyticus Peptostreptococcus anaerobius Porphyromonas asaccharolytica Prevotella melaninogenica Prevotella oralis Propionibacterium acnes Proteus mirabilis Proteus vulgaris Providencia Stuartii Pseudomonas aeruginosa Pseudomonas fluorescens Rhodococcus equi Salmonella dublin Serratia marcescens Shigella flexneri Shigella sonnei Staphylococcus aureus Staphylococcus epidermidis Staphylococcus haemolyticus Staphylococcus intermedius Staphylococcus lugdunensis Staphylococcus saprophyticus Staphylococcus simulans Stenotrophomonas maltophilia Streptococcus acidominimus Streptococcus anginosus Streptococcus bovis Streptococcus canis Streptococcus constellatus Streptococcus cricetus Streptococcus cristatus Streptococcus downei Streptococcus dysgalactiae Streptococcus equi subsp. equi Streptococcus gordonii Streptococcus mitis Streptococcus mutans Streptococcus oralis Streptococcus parasanguinis Streptococcus pneumoniae Streptococcus pseudoporcinus Streptococcus pyogenes Streptococcus ratti</p>
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	<p>Vibrio cholerae</p> <p>Yersinia enterocolitica</p>
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<b>Interfering Agents</b>	Lim broth (Control) Human Amniotic Fluid Human Whole Blood Human Whole Blood (Na Citrate) Human Serum Human Urine sample Human Fecal sample Human Meconium sample Personal Lubricant Lubricating Gel Vaginal Anti-itch Medication Vaginal Antifungal Medication Yeast Gard (Douche) Topical Hemorrhoid Ointments Anti-Diarrheal Medications Deodorant Powder Deodorant Suppositories Deodorant Spray Body Powder Body Oil Neutrogena Spermicidal Foam Oral Laxatives Stool Softener Enema Solution
<b>Kit stability</b>	12 months real time at Closing
<b>System Failure Rate</b>	The assay shall successfully process $\geq 99\%$ of clinical samples in claimed sample types
<b>Controls Failure rate</b>	the control failure rate should be $< 1\%$
<b>Cross contamination</b>	0% run to run sample to sample $< 0.5\%$ concentration 10000X LOD
<b>Transport stability</b>	Specimen stability 2-30°C 60 days. At -20°C to -70°C up to six months
<b>IP</b>	Assays do not infringe any third party IP
<b>Onboard open kit stability</b>	30 days
<b>Control concept</b>	• Full process Positive and negative plus internal controls (ready to use and trackable) – incorporating encapsulated nucleic acid
<b>TAT</b>	$< 65$ minutes
<b>Clinical Sensitivity &amp; Specificity</b>	Sensitivity $> 95\%$ Specificity $> 95\%$ negative predictive value $> 99\%$

<b>COGS</b>	COGS shall be equal or lower than defined in Schedule IV below
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## Schedule IV

COGS specification for all assays

<b>Current COGS (&lt;100k annual)</b>	<p>COGS shall include expenses that are incurred with respect to the Product that are sold related to direct material, direct labor plus an appropriate allocation of fixed and variable production overhead expenses, as determined in accordance with GAAP.</p> <ul style="list-style-type: none"> <li>• <u>Direct material costs</u>: will include the costs incurred in manufacturing or purchasing materials ("raw material"), including shipping costs, supplies, services, sales and excise taxes imposed thereon and customs duty and charges levied by government authorities, and all costs of packaging components.</li> <li>• <u>Direct labor costs</u>: will include a reasonable allocation, in accordance with GAAP or IFRS, as applicable, consistently applied, of actual employment costs of employees engaged in direct manufacturing activities who are directly employed in manufacturing and packaging the Company's product.</li> <li>• <u>Overhead</u> attributable to the Company's product: will be calculated and allocated in a manner consistent with GAAP and will include: <ul style="list-style-type: none"> <li>○ a reasonable allocation of indirect labor not previously included in direct labor costs (such as, but not limited to QA/QC, SCM, Purchase),</li> <li>○ a reasonable allocation of administrative costs,</li> <li>○ and a reasonable allocation of facilities costs (such as, but not limited to depreciation and maintenance of production buildings and equipment, and the cost of production management and administration,</li> </ul> </li> </ul> <p>provided, however, that overhead will not include corporate or administrative overhead, plant capital expenses or startup costs, or costs associated with excess or idle capacity.</p> <p>For the purposes of this definition of COGS, "Product" shall include all components required by customer to run one assay (one test strip well including the respective assays or LDT), one cartridge lane, one capture plate well, all required buffers (e.g. wash, release, respective buffer 1-4), 2 large pipette tips, 1 small pipette tip, and 1/500th waste bag).</p>							
<b>COGS economy of scale (assuming QIAGEN Enzymes)</b>	HBV	HCV	HIV	CTNG	EBV	FluA/B RSV	T. Vag	GBS
<100k annual	\$ 2,84	\$ 3,03	\$ 3,23	\$ 2,52	\$ 2,84	\$ 3,37	\$ 2,52	\$ 2,69
1 Million annual	\$ 2,37	\$ 2,50	\$ 2,76	\$ 2,05	\$ 2,37	\$ 2,85	\$ 2,05	\$ 2,17
5 Million annual	\$ 2,06	\$ 2,24	\$ 2,41	\$ 1,73	\$ 2,06	\$ 2,56	\$ 1,73	\$ 1,86

**Exhibit A**

Form of Surviving Company Certificate of Incorporation

[see attached]

**Exhibit A**

**Certificate of Incorporation of the Surviving Corporation**  
**AMENDED AND RESTATED CERTIFICATE OF INCORPORATION**  
**OF**  
**NEUMODX MOLECULAR, INC.**

**FIRST:** The name of the corporation (hereinafter called the "Corporation") is:  
NEUMODX MOLECULAR, INC.

**SECOND:** The address, including street, number, city, and county, of the registered office of the Corporation in the State of Delaware is 251 Little Falls Drive, City of Wilmington, County of New Castle, Delaware 19808; and the name of the registered agent of the Corporation in the State of Delaware is Corporation Service Company.

**THIRD:** The nature of the business to be conducted and the purposes of the Corporation are to engage in any lawful act or activity or carry on any business for which corporations may be organized under the Delaware General Corporation Law or any successor statute.

**FOURTH:** The total number of shares of all classes of stock which the Corporation shall have authority to issue is [Five Thousand (5,000)], consisting of [5,000] shares of Common Stock, [One Tenth of One Cent (\$.001)] Par Value per share.

**FIFTH:** The Corporation is to have perpetual existence.

**SIXTH:** For the management of the business and for the conduct of the affairs of the Corporation, and in further definition and not in limitation of the powers of the Corporation and of its directors and of its stockholders or any class thereof, as the case may be, conferred by the State of Delaware, it is further provided that:

A. The management of the business and the conduct of the affairs of the Corporation shall be vested in its Board of Directors. The number of directors which shall constitute the whole Board of Directors shall be fixed by, or in the manner provided in, the By-Laws. The phrase "whole Board" and the phrase "total number of directors" shall be deemed to have the same meaning, to wit, the total number of directors which the Corporation would have if there were no vacancies. No election of directors need be by written ballot.

B. After the original or other By-Laws of the Corporation have been adopted, amended or repealed, as the case may be, in accordance with the provisions of Section 109 of the General Corporation Law of the State of Delaware, and, after the Corporation has received any payment for any of its stock, the power to adopt, amend, or repeal the By-Laws of the Corporation may be exercised by the Board of Directors of the Corporation.



C. The books of the Corporation may be kept at such place within or without the State of Delaware as the By-Laws of the Corporation may provide or as may be designated from time to time by the Board of Directors of the Corporation.

**SEVENTH:** The Corporation shall, to the fullest extent permitted by Section 145 of the General Corporation Law of the State of Delaware, as the same may be amended and supplemented from time to time, indemnify and advance expenses to, (i) its directors and officers, and (ii) any person who at the request of the Corporation is or was serving as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, from and against any and all of the expenses, liabilities, or other matters referred to in or covered by said section as amended or supplemented (or any successor), provided, however, that except with respect to proceedings to enforce rights to indemnification, the By-Laws of the Corporation may provide that the Corporation shall indemnify any director, officer or such person in connection with a proceeding (or part thereof) initiated by such director, officer or such person only if such proceeding (or part thereof) was authorized by the Board of Directors of the Corporation. The Corporation, by action of its Board of Directors, may provide indemnification or advance expenses to employees and agents of the Corporation or other persons only on such terms and conditions and to the extent determined by the Board of Directors in its sole and absolute discretion. The indemnification provided for herein shall not be deemed exclusive of any other rights to which those indemnified may be entitled under any By-Law, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in their official capacity and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be a director, officer, employee, or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

**EIGHTH:** No director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director except to the extent that exemption from liability or limitation thereof is not permitted under the General Corporation Law of the State of Delaware as in effect at the time such liability or limitation thereof is determined. No amendment, modification or repeal of this Article shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment, modification or repeal. If the General Corporation Law of the State of Delaware is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended.

**NINTH:** From time to time any of the provisions of this Amended and Restated Certificate of Incorporation may be amended, altered or repealed, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted in the manner and at the time prescribed by said laws, and all rights at any time conferred upon the stockholders of the Corporation by this Amended and Restated Certificate of Incorporation are granted subject to the provisions of this Article.

**Exhibit B**

Form of Option Cancellation Agreement

[see attached]

**EXHIBIT B**

**OPTION CANCELLATION AGREEMENT**

THIS OPTION CANCELLATION AGREEMENT ("Agreement") is made as of \_\_\_\_\_, [2019/2020], by and between NeuMoDx Molecular, Inc., a Delaware corporation (the "Company"), and the person identified under the heading "Optionee" on the signature page hereto (the "Optionee"). All capitalized terms used but not otherwise defined herein shall have the meaning set forth in the Merger Agreement (as defined below).

WHEREAS, the Company has entered into an Agreement and Plan of Merger (the "Merger Agreement"), dated as of \_\_\_\_\_, 2018, by and among the Company, QIAGEN North American Holdings, Inc., a California corporation (the "Purchaser"), NALEX Merger Sub, Inc., a Delaware corporation ("Merger Sub"), and Shareholder Representative Services LLC (the "Sellers' Representative"), pursuant to which Purchaser, Merger Sub and the Company intend to effect a merger of Merger Sub with and into the Company;

WHEREAS, the Company has granted to the Optionee an option to purchase [ ] shares of the Company's common stock (the "Option");

WHEREAS, in connection with the Closing, the Company and the Optionee desire to cancel the Option on the terms set forth herein; and

WHEREAS, provided that such Option is outstanding at the time of the Closing, to the extent that any portion of the Option is unvested at the time of the Closing, such unvested portion shall accelerate and be eligible for the payment as set forth in this Agreement.

NOW, THEREFORE, the parties hereto agree as follows:

1. Cancellation. The Optionee hereby irrevocably and unconditionally cancels, surrenders and waives all of the Optionee's rights under the Option, effective upon and subject to the Closing (the "Cancellation").

2. Consideration. In consideration of the Cancellation, at the Closing, Optionee shall be entitled to receive the Merger Consideration in respect of the Option as set forth in the Merger Agreement. Optionee acknowledges and agrees that this Agreement and the right to receive the Merger Consideration upon the Cancellation of the Option only applies to the Option to the extent that the Option is outstanding as of the Closing. Whether the Option is outstanding as of the Closing will be governed by, and determined by reference to, the Company's 2012 Incentive Stock and Awards Plan.

3. Optionee's Representation and Warranties. Optionee hereby represents and warrants that the following statements are true as of the Closing:

(a) Power and Authority. Optionee possesses all power and authority to execute and deliver this Agreement and to perform each of the transactions contemplated hereby.

(b) Authorization; No Breach. This Agreement constitutes the valid and binding obligation of Optionee, enforceable in accordance with its terms. The execution and delivery by Optionee of this Agreement, and compliance with the terms hereof by Optionee, do not and shall not (i) conflict with or result in a breach of the terms, conditions or provisions of, (ii) constitute a default under, (iii) result in a violation of or (iv) require any authorization, consent, approval, exemption or other action by or notice to any court or administrative or governmental body pursuant to, any law, statute, rule or regulation to which Optionee is subject, or any agreement, organizational document, instrument, order, judgment or decree to which Optionee is a party or by which it is bound.

(c) Title; etc. Optionee is the record and beneficial owner of, and has good and marketable title to, the Option, free and clear of all Liens. After giving effect to the Cancellation and the transactions contemplated in the Merger Agreement, neither Optionee nor any Affiliate of Optionee will have any interest in any capital stock or other security of the Company.

#### 4. Merger Agreement and Other Transaction Related Documents.

(a) The Optionee hereby agrees to be bound by the terms of the Merger Agreement as an "Option Holder" thereunder, including, without limitation, Article VII, by execution of a joinder to the Merger Agreement, attached hereto as Exhibit A (the "Joinder Agreement"). A copy of the Merger Agreement has been provided to Optionee (without schedules or attachments). As a condition to the receipt of the Merger Consideration, by executing the Joinder Agreement, Optionee shall be agreeing to the terms of the release set forth therein.

(b) The Optionee acknowledges the appointment of the Sellers' Representative as the representative and agent of the Sellers and the Option Holders who have received Merger Consideration in the Merger as set forth in the Merger Agreement.

(c) In connection with the consummation of the transactions contemplated by the Merger Agreement, the Sellers and Option Holders have entered into a Contribution and Indemnity Agreement (the "Contribution Agreement"), effective as of the same date as the Merger Agreement. The Optionee hereby agrees to be bound to the terms of the Contribution Agreement by execution of a joinder signature page to the Contribution Agreement, attached hereto as Exhibit B. By execution of the joinder signature page to the Contribution Agreement the Optionee will become a party to the Contribution Agreement as a "Seller". A copy of the Contribution Agreement has been provided to Optionee.

(d) Optionee acknowledges and agrees that this Agreement shall not be effective unless the Optionee executes this Agreement, the Joinder Agreement, and the joinder signature page to the Contribution Agreement.

5. Delivery of Consideration. Optionee understands and acknowledges that the Merger Consideration will be paid to the Optionee through the Company and its payroll functions as provided in the Merger Agreement.

6. Complete Agreement. This Agreement, the Joinder Agreement, the Contribution Agreement and the Merger Agreement and the agreements executed in connection

therewith embody the complete agreement and understanding among the parties and supersede and preempt any prior understandings, agreements or representations by or among the parties, written or oral, which may have related to the subject matter hereof in any way.

7. Counterparts. This Agreement may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one and the same agreement.

8. Successors and Assigns. Except as otherwise provided herein, this Agreement shall bind and inure to the benefit of and be enforceable by the Optionee, the Company and their respective successors and assigns; provided that the rights and obligations of the Optionee and the Company under this Agreement shall not be assignable without the prior written consent of the other party.

9. Choice of Law. The corporate law of the State of Delaware will govern all questions concerning the relative rights of the Company and the Optionee. All other questions concerning the construction, validity and interpretation of this Agreement will be governed by and construed in accordance with the internal laws of the State of Delaware, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of Delaware.

10. Amendment and Waiver. The provisions of this Agreement may be amended and waived only with the prior written consent of the Company and the Optionee.

11. Effectiveness. This Agreement shall be void and of no force and effect, including any acceleration of the Option referenced in this Agreement, if the Closing pursuant to the Merger Agreement fails to occur for any reason. THERE IS NO GUARANTEE THAT THE CLOSING WILL OCCUR.

12. Third Party Beneficiary. From and after the Closing, the Purchaser shall be an intended third-party beneficiary to this Agreement and the Joinder Agreement.

\* \* \* \* \*

IN WITNESS WHEREOF, the parties hereto have executed this Option Cancellation Agreement on the date first written above.

NEUMODX MOLECULAR, INC.

By \_\_\_\_\_  
Name: \_\_\_\_\_  
Its: \_\_\_\_\_

OPTIONEE:

SIGN HERE	
Dated:	_____ Signature of Optionholder
Address:	_____ Print Name
(Zip Code)	
Area Code and Telephone No.:	
Social Security Number:	

ACKNOWLEDGED AND AGREED:

QIAGEN North American Holdings, Inc.

By \_\_\_\_\_  
Name: \_\_\_\_\_  
Its: \_\_\_\_\_

NALEX Merger Sub, Inc.

By \_\_\_\_\_  
Name: \_\_\_\_\_  
Its: \_\_\_\_\_

[Signature Page to Option Cancellation Agreement]

Exhibit A

JOINDER AGREEMENT ATTACHED AS EXHIBIT D TO  
MERGER AGREEMENT



Exhibit B

JOINDER SIGNATURE PAGE TO CONTRIBUTION AGREEMENT

The undersigned hereby agrees to become a party to that certain Contribution and Indemnity Agreement dated as of [\_\_\_\_], 2018 (the "Contribution Agreement") by and among the stockholders and option holders of NeuMoDx Molecular, Inc., a Delaware corporation. From and after the undersigned's execution and delivery of this signature page, the undersigned shall be a party to the Contribution Agreement as a "Seller" for all purposes of the Contribution Agreement. This signature page shall be deemed to have been delivered by the undersigned as of the date of the Contribution Agreement.

\_\_\_\_\_  
(Print Name of Seller)

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Print Name of Signatory)

\_\_\_\_\_  
(Print Title of Signatory)

**IN WITNESS WHEREOF**, the undersigned has duly executed this Release and Waiver as of the date set forth below.

\_\_\_\_\_  
(print or type name)

\_\_\_\_\_  
(signature)

\_\_\_\_\_  
(date)

81126211v.2

3629019.v8

**Exhibit B-2**

Form of Warrant Cancellation Agreement

[see attached]

**EXHIBIT B-2****WARRANT CANCELLATION AGREEMENT**

This Warrant Cancellation Agreement (this “Agreement”) is entered into as of [●], by and between NeuMoDx Molecular, Inc., a Delaware corporation (the “Company”), and the undersigned holders (the “Warrantholders,” and together with the Company, the “Parties”) of certain warrants listed on Exhibit A of this Agreement (each, a “Q-1 Warrant” and collectively, the “Q-1 Warrants”) to purchase the number of shares of the Company’s Series Q-1 Preferred Stock, par value \$0.0001 per share (the “Series Q-1 Preferred”), granted on the date(s) and at the exercise price (the “Exercise Price”) listed on Exhibit A hereto. All capitalized terms not otherwise defined herein shall have the meanings ascribed to them in the Merger Agreement (as defined below).

**WHEREAS**, the Company granted the Warrantholders the Q-1 Warrants in connection with that certain Loan and Security Agreement, as supplemented by that Supplement to the Loan and Security Agreement, both dated as of [●] (together, the “Loan Agreement”);

**WHEREAS**, the Company has entered into an Agreement and Plan of Merger dated as of [●] (the “Merger Agreement”), by and among the Company, QIAGEN North American Holdings, Inc. (“Purchaser”) and the other parties listed therein, pursuant to which, among other matters, Purchaser shall acquire all of the outstanding shares of capital stock of the Company and Company shall become a wholly owned subsidiary of Purchaser;

**WHEREAS**, in connection with the consummation of the transactions contemplated under the Merger Agreement, the Q-1 Warrants, to the extent not exercised or converted into shares of the Company’s capital stock, will be cancelled and terminated and converted at the Closing Date into the right to receive a cash amount equal to the Warrant Cancellation Amount, as such term is defined in the Loan Agreement.

**NOW, THEREFORE**, in consideration of the mutual promises and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Effectiveness; Incorporation by Reference; Term. This Agreement shall be binding on the Parties on the date it is executed by the Parties. The terms of this Agreement shall become effective immediately prior and subject to the Closing. Up to and until the Closing, the terms of the Loan Agreement and the Q-1 Warrants shall continue to govern all Q-1 Warrants.

2. Termination of the Q-1 Warrants. All of the Q-1 Warrants held by the Warrantholders will be automatically terminated as of the Closing with no further action required by either the Company, Purchaser or the Warrantholders. The Warrantholders agree to waive, and hereby waive, any and all rights that any of them may have pursuant to the Q-1 Warrants, including, without limitation, any notice requirements or other provisions contained in any agreements relating to the Q-1 Warrants. The Warrantholders hereby acknowledge and agree that the consideration specified in Section 3 below and as more fully provided for in the Merger Agreement and the Loan Agreement represents full and final satisfaction of all of the Company’s obligations to the Warrantholders in respect of the Q-1 Warrants, including, without limitation, in connection with the transactions contemplated by the Merger Agreement. Effective upon the termination of the Q-1 Warrants at the Closing, the Q-1 Warrants will have no further force or effect and

neither the Company nor Purchaser will have any further obligations to Warrantholders with respect to the Q-1 Warrants.

3. Consideration. The Company and Warrantholders hereby irrevocably acknowledge and agree that upon termination of the Q-1 Warrants at the Closing, the Warrantholders shall be entitled to receive, subject to the terms of the Loan Agreement, the Warrant Cancellation Amounts set forth on Exhibit A opposite the applicable Q-1 Warrant. The Warrantholders hereby expressly agree that the Warrant Cancellation Amount for each Q-1 Warrant is subject to the terms of the Merger Agreement. The Warrant Cancellation Amounts shall be paid to Warrantholders by the Company. The Warrantholders acknowledge that the execution and delivery of this Agreement are conditions precedent to the Company's obligation to pay the Warrant Cancellation Amounts.

4. Representations and Warranties. Each Warrantholder hereby represents and warrants that: (i) it is the sole beneficial and record owner and holder of its respective Q-1 Warrant, free and clear of all liens, claims, restrictions, pledges, security interests and encumbrances; (ii) it has the full power, authority and legal right to execute and deliver this Agreement and perform the terms hereof; (iii) this Agreement has been duly executed and delivered by the Warrantholder and constitutes its valid, binding and enforceable obligation; (iv) there is no contractual obligation, or obligation under any law or court order, pursuant to which such Warrantholder has, directly or indirectly, granted any option, warrant or other right to any Person to acquire any of the Q-1 Warrant issued to such Warrantholder or shares of capital stock issuable upon exercise of such Q-1 Warrant; (v) the execution, delivery and performance of this Agreement by Warrantholder does not and will not, (a) violate any law or any order, judgment or decree of any court or other governmental or regulatory authority, or (b) violate or result in a breach of or constitute (with due notice or lapse of time or both) a default under any contract, lease, loan agreement, mortgage, security agreement, trust indenture or other agreement or instrument to which such Warrantholder is a party or by which it is bound; and (vi) upon the termination of its Q-1 Warrant in connection with this Agreement, it will hold no other options or rights to purchase capital stock or other equity interests in the Company or under any plan, award, grant, agreement or understanding.

5. Disclosure. The Warrantholders hereby acknowledge that they have received and reviewed the Merger Agreement, and have had an opportunity to ask representatives of the Company questions with regard to the transactions contemplated by the Merger Agreement and that all such questions have been answered fully and to the satisfaction of the Warrantholders.

6. Release of Claims. As of and conditioned upon the Closing, the Warrantholders, for each of them and their respective Affiliates, partners, heirs, beneficiaries, successors and assigns, if any, hereby releases and absolutely forever discharges each of the Company and Purchaser, and each of their respective Affiliates and the shareholders, directors, officers, employees, agents and representatives of the Company and Purchaser and each of their respective Affiliates (each, a "Released Party") from any and all losses, lawsuits, claims, counterclaims, actions, demands, assessments, proceedings, arbitrations, investigations, damages, liabilities, obligations, deficiencies, taxes, costs and expenses of any nature whatsoever, whether known or unknown, suspected or unsuspected, that any of them now has, at any time previously had or may have in the future as a shareholder, director, officer, employee, agent or representative of the Company or Purchaser, arising by virtue of or in any matter related to or arising from the undersigned's ownership of any capital stock of, or other equity or voting securities or interests in, or any convertible securities to purchase equity in, the Company on or prior to the Closing, including, but not limited to, any claim that the undersigned owns or has the right to acquire any capital stock of, or other equity or voting securities or interests in, the Company (collectively, "Released Matters").

7. Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware (without giving effect to principles of conflicts of laws).

8. Severable Provisions; Headings; Construction. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon such determination that any term or other provision is invalid, illegal or unenforceable, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible. The headings in this Agreement are for reference only and shall not affect the interpretation of this Agreement.

9. Entire Agreement. This Agreement, the Loan Agreement and the Merger Agreement constitute the entire agreement between the Parties hereto pertaining to the subject matter hereof, and supersede all prior and contemporaneous agreements, understandings, negotiations and discussions, whether oral or written, of the Parties including, without limitation, any agreement relating to the Warrants. No supplement, modification or waiver or termination of this Agreement or any provision hereof shall be binding unless executed in writing by the Parties to be bound thereby. This Agreement shall be binding upon all successors and assigns of the Parties.

10. Third Party Beneficiary. The Warrantholders acknowledge and agree that each Released Party, including, without limitation, the Purchaser is a third party beneficiary of the representations, warranties, covenants and agreements of the Warrantholders set forth in this Agreement.

11. Further Assurances. The Warrantholders will, upon request, execute and deliver any additional documents reasonably deemed appropriate or necessary by the Company in connection with the cancellation of the Warrants.

12. Counterparts and Facsimile or Electronic Transmission. This Agreement may be executed in two or more counterparts, any one of which need not contain the signatures of all Parties, but all of which counterparts when taken together will constitute one and the same instrument. Delivery of an executed counterpart of a signature page to this Agreement by facsimile or electronic transmission in a pdf. file or other similar image file, shall be effective as delivery of a manually executed counterpart thereof.

*[Remainder of Page Intentionally Left Blank]*

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first set forth above.

**NEUMODX MOLECULAR, INC.**

By: \_\_\_\_\_  
Name:  
Title:

**WARRANTHOLDERS**

VENTURE LENDING & LEASING XIII, LLC

By: Westech Investment Advisors LLC  
Its: Managing Member

By: \_\_\_\_\_  
Name:  
Title:

VENTURE LENDING & LEASING IX, LLC

By: Westech Investment Advisors LLC  
Its: Managing Member

By: \_\_\_\_\_  
Name:  
Title:

[Signature Page to Warrant Cancellation Agreement]



Exhibit A

## WARRANTS

Warrantholder Name	Number of Shares*	Exercise Price per Share	Warrant Cancellation Amount
[•]	[•]	\$[•]	\$[•]

**Exhibit C**

Form of Escrow Agreement

[see attached]

## EXHIBIT C

### ESCROW AGREEMENT

THIS ESCROW AGREEMENT (the "Escrow Agreement") is entered into and effective this [•] day of [•], [20[\_\_\_]], by and among SunTrust Bank (the "Escrow Agent"), QIAGEN North American Holdings, Inc. ("Purchaser") and Shareholder Representative Services LLC (the "Stockholder Representative" and together with the Purchaser, the "Parties") solely in its capacity as the representative of the Company's holders of capital stock and options to acquire capital stock (the "Securityholders");

WHEREAS,

Purchaser and the Stockholder Representative have entered into that certain Agreement and Plan of Merger, dated as of [•], 2018 (the "Acquisition Agreement"), by and among Purchaser, [Merger Sub], NeuMoDx Molecular, Inc. and the Stockholder Representative.

Purchaser and the Stockholder Representative desire for the Escrow Agent to open an account (the "Escrow Account") into which Purchaser will deposit funds to be held, disbursed and invested by the Escrow Agent in accordance with this Escrow Agreement.

Purchaser and the Stockholder Representative have entered into that certain Payments Administration Agreement, dated as of [•], by and among Acquiom Financial LLC ("Payments Administrator"), Purchaser and the Stockholder Representative (the "Payments Agreement") pursuant to which Payments Administrator has established the account described on Exhibit B (the "Paying Account") for the purpose of receiving funds disbursed pursuant to this Escrow Agreement.

NOW, THEREFORE, in consideration of the premises herein, the parties hereto agree as follows:

#### I. Terms and Conditions

1.1. Purchaser and the Stockholder Representative hereby appoint the Escrow Agent as their escrow agent, and the Escrow Agent hereby accepts its duties as provided herein. The initial escrow deposit will be \$[•] (the "Escrow Fund").

1.2. Purchaser shall from time to time remit funds to the Escrow Agent, using the wire instructions set forth below, to be held by the Escrow Agent and disbursed and invested as provided in this Escrow Agreement.

SunTrust Bank  
ABA: 061000104  
Account: 9443001321  
Account Name: Escrow Services  
Reference: Qiagen-NeuMoDx Escrow  
Attention: Byron Roldan

1.3. Within two Business Days (except as provided below) of receipt of either (a) written instructions ("Joint Instructions"), signed by an authorized representative of each of Purchaser and the Stockholder Representative (a list of whom are provided in Exhibit A-1 and Exhibit A-2), or (b) a written notice from either the Purchaser or the Stockholder Representative evidencing a Final

Decision (as defined below), which is certified by the party delivering such notice that the Final Decision is accurately reflected in the notice, in each case specifying the amount to be disbursed and identifying the party to whom the disbursement shall be made, which shall be either Purchaser or the Paying Account, Escrow Agent shall disburse funds held in the Escrow Account as provided in such Joint Instructions or Final Decision in accordance with this Section 1.3, but only to the extent that funds are collected and available. Disbursements to Purchaser shall be made in accordance with the payment instructions set forth in such Joint Instructions or otherwise provided by Purchaser or in the Final Decision. Disbursements to the Paying Account shall be deposited by the Escrow Agent into the account designated in Exhibit B on the same Business Day as the Escrow Agent receives such Joint Instructions or Final Decision, or the next Business Day if such Joint Instructions or Final Decision are received after 3:00 p.m. Eastern Time. The Escrow Agent shall have no responsibility for, and is hereby relieved of all liability to Purchaser, the Stockholder Representative and all other persons and entities with respect to, the manner in which funds are applied or disbursed from the Paying Account as directed by Payments Administrator. For purposes of this Escrow Agreement, "Business Day" shall mean any day other than a Saturday, Sunday or any other day on which the Escrow Agent located at the notice address set forth in Section 4.4 is authorized or required by law or executive order to remain closed. "Final Decision" shall mean a final non-appealable judgment or decree of a court of competent jurisdiction with the authority to render a decision binding upon the parties delivered by the Purchaser or the Stockholder Representative to the Escrow Agent and accompanied by a written instruction from such party to the Escrow Agent to effectuate such judgment or decree.

## **II. Provisions as to the Escrow Agent**

2.1. This Escrow Agreement expressly and exclusively sets forth the duties of the Escrow Agent with respect to any and all matters pertinent hereto and no implied duties or obligations shall be read into this Escrow Agreement against the Escrow Agent. In performing its duties under this Escrow Agreement, or upon the claimed failure to perform its duties, the Escrow Agent shall have no liability except for the Escrow Agent's willful misconduct or gross negligence. In no event shall the Escrow Agent be liable for incidental, indirect, special, consequential or punitive damages of any kind whatsoever (including but not limited to lost profits), even if the Escrow Agent has been advised of the likelihood of such loss or damage and regardless of the form of action. The Escrow Agent shall have no liability with respect to the transfer or distribution of any funds effected by the Escrow Agent pursuant to wiring or transfer instructions provided to the Escrow Agent in accordance with the provisions of this Escrow Agreement. Any wire transfers of funds made by the Escrow Agent pursuant to this Escrow Agreement will be made subject to and in accordance with the Escrow Agent's usual and ordinary wire transfer procedures in effect from time to time. No provision of this Escrow Agreement shall require the Escrow Agent to risk or advance its own funds or otherwise incur any financial liability or potential financial liability in the performance of its duties or the exercise of its rights under this Escrow Agreement. The Escrow Agent shall not be obligated to take any legal action or to commence any proceedings in connection with this Escrow Agreement or any property held hereunder or to appear in, prosecute or defend in any such legal action or proceedings.

2.2. Purchaser and the Stockholder Representative acknowledge and agree that the Escrow Agent acts hereunder as a depository only, and is not responsible or liable in any manner whatsoever for the sufficiency, correctness, genuineness or validity of the subject matter of this Escrow Agreement or any part thereof, or of any person executing or depositing such subject matter.

2.3. This Escrow Agreement constitutes the entire agreement between the Escrow Agent and Purchaser and the Stockholder Representative in connection with the subject matter of this Escrow Agreement, and no other agreement entered into between Purchaser and the Stockholder

Representative, or either of them, including, without limitation, the Payments Agreement and the Acquisition Agreement, shall be considered as adopted or binding, in whole or in part, upon the Escrow Agent notwithstanding that any such other agreement may be deposited with the Escrow Agent or the Escrow Agent may have knowledge thereof.

2.4. The Escrow Agent shall be protected in acting upon any written instruction, notice, request or instrument which the Escrow Agent in good faith believes to be genuine and what it purports, to be, including, but not limited to, items directing investment or non-investment of funds, items requesting or authorizing release, disbursement or retainage of the subject matter of this Escrow Agreement and items amending the terms of this Escrow Agreement.

2.5. The Escrow Agent may consult with legal counsel in the event of any dispute or question as to the construction of any of the provisions hereof or its duties hereunder, and it shall incur no liability and shall be fully protected in acting in accordance with the advice of such counsel.

2.6. In the event of any disagreement between Purchaser and the Stockholder Representative, or between either of them and any other party, resulting in adverse claims or demands being made in connection with the matters covered by this Escrow Agreement, or in the event that the Escrow Agent, in good faith, be in doubt as to what action it should take hereunder, the Escrow Agent may, at its option, refuse to comply with any claims or demands on it, or refuse to take any other action hereunder, so long as such disagreement continues or such doubt exists, and in any such event, the Escrow Agent shall not be or become liable in any way or to any party for its failure or refusal to act, and the Escrow Agent shall be entitled to continue to refrain from acting until (i) the rights of Purchaser and the Stockholder Representative and all other interested parties shall have been fully and finally adjudicated by a court of competent jurisdiction, or (ii) all differences shall have been adjudged and all doubt resolved by agreement among Purchaser and the Stockholder Representative and all other interested parties, and the Escrow Agent shall have been notified thereof in writing signed by Purchaser and the Stockholder Representative. Notwithstanding the preceding, the Escrow Agent may in its discretion obey the order, judgment, decree or levy of any court, whether with or without jurisdiction, or of an agency of the United States or any political subdivision thereof, or of any agency of any State of the United States or of any political subdivision thereof, and the Escrow Agent is hereby authorized in its sole discretion, to comply with and obey any such orders, judgments, decrees or levies. The rights of the Escrow Agent under this sub-paragraph are cumulative of all other rights which it may have by law or otherwise.

In the event of any disagreement or doubt, as described above, the Escrow Agent shall have the right, in addition to the rights described above and at the election of the Escrow Agent, to tender into the registry or custody of any court having jurisdiction, all funds and property held under this Escrow Agreement, and the Escrow Agent shall have the right to take such other legal action as may be appropriate or necessary, in the sole discretion of the Escrow Agent. Upon such tender, Purchaser and the Stockholder Representative agree that the Escrow Agent shall be discharged from all further duties under this Escrow Agreement.

2.7. Purchaser and the Stockholder Representative (solely on behalf of the Securityholders and in its capacity as the Stockholder Representative, not in its individual capacity) jointly and severally agree to defend, indemnify and hold harmless the Escrow Agent and each of the Escrow Agent's officers, directors, agents and employees (the "Indemnified Parties") from and against any and all losses, liabilities, claims made by any Party or any other person or entity, damages, expenses and costs (including, without limitation, attorneys' fees and expenses) of every nature whatsoever (collectively, "Losses") which any such Indemnified Party may incur and which arise directly or indirectly from this Escrow Agreement or which arise directly or indirectly by virtue of the Escrow

Agent's undertaking to serve as the Escrow Agent hereunder; *provided, however*, that no Indemnified Party shall be entitled to indemnity with respect to Losses that have been finally adjudicated by a court of competent jurisdiction to have been directly caused by such Indemnified Party's gross negligence or willful misconduct. The provisions of this section shall survive the termination of this Escrow Agreement and any resignation or removal of the Escrow Agent.

2.8. Any entity into which the Escrow Agent may be merged or converted or with which it may be consolidated, or any entity to which all or substantially all the escrow business of the Escrow Agent may be transferred, shall be the Escrow Agent under this Escrow Agreement without further act.

2.9. The Escrow Agent may resign at any time from its obligations under this Escrow Agreement by providing written notice to Purchaser and the Stockholder Representative. Such resignation shall be effective on the date set forth in such written notice, which shall be no earlier than thirty (30) days after such written notice has been furnished. Purchaser and the Stockholder Representative shall promptly appoint a successor escrow agent. In the event no successor escrow agent has been appointed on or prior to the date such resignation is to become effective, the Escrow Agent shall be entitled to tender into the custody of any court of competent jurisdiction all funds and other property then held by the Escrow Agent hereunder and the Escrow Agent shall thereupon be relieved of all further duties and obligations under this Escrow Agreement. The Escrow Agent shall have no responsibility for the appointment of a successor escrow agent hereunder.

### **III. Compensation of the Escrow Agent**

3.1. The Escrow Agent shall not charge fees to Purchaser and the Stockholder Representative for the services provided by it hereunder; *provided, however*, that the terms of this paragraph shall not in any way limit the rights of the Escrow Agent to indemnification as set forth in this Escrow Agreement.

### **IV. Miscellaneous**

4.1. The Escrow Agent shall invest all funds held pursuant to this Escrow Agreement in accordance with Exhibit C. Instructions to make any other investment must be in writing and signed by each of the Parties. Purchaser and the Stockholder Representative recognize and agree that the Escrow Agent will not provide supervision, recommendations or advice relating to the investment of moneys held hereunder or the purchase, sale, retention or other disposition of any investment, and the Escrow Agent shall not be liable to Purchaser or the Stockholder Representative or any other person or entity for any loss incurred in connection with any such investment. The Escrow Agent is hereby authorized to execute purchases and sales of investments through the facilities of its own trading or capital markets operations or those of any affiliated entity. The Escrow Agent, Payments Administrator and/or any of their affiliates may receive compensation with respect to any investment directed hereunder including without limitation charging any applicable agency fee in connection with each transaction. The Escrow Agent is authorized and directed to sell or redeem any investments as it deems necessary to make any payments or distributions required under this Escrow Agreement.

4.2. The Escrow Agent shall provide monthly reports of transactions and holdings to Purchaser and the Stockholder Representative as of the end of each month, at the address provided by Purchaser and the Stockholder Representative.

4.3. Purchaser and the Stockholder Representative agree that, subject to the terms and conditions of this Escrow Agreement, the owner of the funds held in Escrow is the Purchaser and all interest and income from the investment of the funds shall be reported as having been earned by Purchaser as of



the end of the calendar year in which it was earned, whether or not such income was disbursed during such calendar year, to the extent required by the United States Internal Revenue Service (“IRS”). On or before the execution and delivery of this Escrow Agreement, each of Purchaser and Stockholder Representative shall provide to the Escrow Agent a correct, duly completed, dated and executed current IRS Form W-9 or Form W-8, whichever is appropriate or any successor forms thereto, in a form and substance satisfactory to the Escrow Agent including appropriate supporting documentation and/or any other form, document, and/or certificate required or reasonably requested by the Escrow Agent to validate the form provided. Notwithstanding anything to the contrary herein provided, except for the delivery and filing of tax information reporting forms required pursuant to the Internal Revenue Code of 1986, as amended, to be delivered and filed with the IRS by the Escrow Agent, as escrow agent hereunder, the Escrow Agent shall have no duty to prepare or file any Federal or state tax report or return with respect to any funds held pursuant to this Escrow Agreement or any income earned thereon. Purchaser and the Stockholder Representative (solely on behalf of the Securityholders and in its capacity as the Stockholder Representative, not in its individual capacity), jointly and severally, agree to indemnify, defend and hold the Escrow Agent harmless from and against any tax, late payment, interest, penalty or other cost or expense that may be assessed against the Escrow Agent on or with respect to the funds held under this Escrow Agreement or any earnings or interest thereon unless such tax, late payment, interest, penalty or other cost or expense was finally adjudicated by a court of competent jurisdiction to have been directly caused by the gross negligence or willful misconduct of the Escrow Agent. The indemnification provided in this section is in addition to the indemnification provided to the Escrow Agent elsewhere in this Escrow Agreement and shall survive the resignation or removal of the Escrow Agent and the termination of this Escrow Agreement.

4.4. Any notice, request for consent, report, or any other communication required or permitted in this Escrow Agreement shall be in writing and shall be deemed to have been given when delivered (i) personally, (ii) by facsimile transmission with written confirmation of receipt, (iii) by electronic mail to the e-mail address given below, and written confirmation of receipt is obtained promptly after completion of the transmission, (iv) by overnight delivery with a reputable national overnight delivery service, or (v) by United States mail, postage prepaid, or by certified mail, return receipt requested and postage prepaid, in each case to the appropriate address set forth below or at such other address as any party hereto may have furnished to the other parties hereto in writing:

If to the Escrow Agent:

SunTrust Bank  
Attn: Escrow Services  
919 East Main Street, 5<sup>th</sup> Floor  
Richmond, Virginia 23219  
Client Manager: Byron Roldan  
Telephone: (804) 782-5404  
Facsimile: (804) 225-7141  
Email: byron.roldan@suntrust.com

with a copy (which shall not constitute notice) to:

Acquiom Clearinghouse LLC  
950 17<sup>th</sup> Street, Suite 1400  
Denver, CO 80202  
Attention: [Ali Bryson / Daren Di Nicola / Jennifer Kelley / Luda Semenova]  
Telephone: [•]; (303) 222-2080



Facsimile: (720) 554-7828

Email: [abryson@srsacquiom.com / ddinicola@srsacquiom.com / jkelley@srsacquiom.com / luda.semenova@srsacquiom.com], cc: paymentsadministration@srsacquiom.com

If to Purchaser:

Dr. Philipp von Hugo  
QIAGEN GmbH  
QIAGEN Strasse 1  
40724 Hilden  
Germany  
Philipp von Hugo: philipp.hugo@qiagen.com  
Telephone: 011 49 2103 29 11844  
Fax: 011 49 2103 29 21844

With a copy, which shall not constitute notice to Purchaser, to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.  
One Financial Center  
Boston, MA 02111  
Attn: Daniel Follansbee, Esq.  
Email: DHFollansbee@mintz.com  
Telephone: (617) 348-4474  
Fax: (617) 542-2241

If to the Stockholder Representative:

Shareholder Representative Services LLC  
950 17th Street, Suite 1400  
Denver, CO, 80202  
Attn: Managing Director  
Email: deals@srsacquiom.com  
Fax: (303) 623-0294  
Telephone: (303) 648-4085

With a copy, which shall not constitute notice to the Sellers' Representative, to:

Jaffe, Raitt, Heuer & Weiss, P.C.  
27777 Franklin Road, Ste. 2500  
Southfield, MI 48034-8214  
Attn: Sara Kruse, Esq.  
Email: skruse@jaffelaw.com  
Telephone: (248) 351-3000  
Fax: (248) 351-3082

Any party may unilaterally designate a different address by giving notice of each change in the manner specified above to each other party.

4.5. This Escrow Agreement is intended to be construed according to the laws of the Commonwealth of Virginia. Except as permitted in Section 2.8, neither this Escrow Agreement nor any rights or obligations hereunder may be assigned by any party hereto without the express written

consent of each of the other parties hereto. This Escrow Agreement shall inure to and be binding upon the parties hereto and their respective successors, heirs and permitted assigns.

4.6. The terms of this Escrow Agreement may be altered, amended, modified or revoked only by an instrument in writing signed by all the parties hereto.

4.7. If any provision of this Escrow Agreement shall be held or deemed to be or shall in fact, be illegal, inoperative or unenforceable, the same shall not affect any other provision or provisions herein contained or render the same invalid, inoperative or unenforceable to any extent whatsoever.

4.8. This Escrow Agreement is for the sole benefit of the Indemnified Parties, Purchaser, the Stockholder Representative and the Escrow Agent, and their respective successors and permitted assigns, and nothing herein, express or implied, is intended to or shall confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Escrow Agreement.

4.9. No party to this Escrow Agreement shall be liable to any other party hereto for losses due to, or if it is unable to perform its obligations under the terms of this Escrow Agreement because of, acts of God, fire, war, terrorism, floods, strikes, electrical outages, equipment or transmission failure, or other causes reasonably beyond its control.

4.10. This Escrow Agreement shall terminate upon the distribution of all funds and property held under this Escrow Agreement or upon the earlier joint written instructions of the parties hereto (other than the Escrow Agent).

4.11. All titles and headings in this Escrow Agreement are intended solely for convenience of reference and shall in no way limit or otherwise affect the interpretation of any of the provisions hereof.

4.12. This Escrow Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

4.13. Contemporaneously with the execution and delivery of this Escrow Agreement and, if necessary, from time to time thereafter, each of the parties to this Escrow Agreement (other than the Escrow Agent) shall execute and deliver to the Escrow Agent a Certificate of Incumbency substantially in the form of Exhibit A-1 and A-2 hereto (a "Certificate of Incumbency") for the purpose of establishing the identity and authority of persons entitled to issue notices, instructions or directions to the Escrow Agent on behalf of each such party. Until such time as the Escrow Agent shall receive an amended Certificate of Incumbency replacing any Certificate of Incumbency theretofore delivered to the Escrow Agent, the Escrow Agent shall be fully protected in relying, without further inquiry, on the most recent Certificate of Incumbency furnished to the Escrow Agent. Whenever this Escrow Agreement provides for joint written notices, joint written instructions or other joint actions to be delivered to the Escrow Agent, the Escrow Agent shall be fully protected in relying, without further inquiry, on any joint written notice, instructions or action executed by persons named in such Certificate of Incumbency.

**IMPORTANT INFORMATION ABOUT PROCEDURES FOR OPENING A NEW ACCOUNT:**

**To help the government fight the funding of terrorism and money laundering activities, Federal law requires all financial institutions to obtain, verify and record information that identifies**

**each person who opens an account. When a party opens an account, the Escrow Agent will ask for each party's name, address, date of birth, or other appropriate information that will allow the Escrow Agent to identify such party. The Escrow Agent may also ask to see each party's driver's license or other identifying documents.**

IN WITNESS WHEREOF, the parties hereto have caused this Escrow Agreement to be executed as of the date first above written.

SUNTRUST BANK, as the Escrow Agent

By: \_\_\_\_\_  
Name:  
Title:

QIAGEN NORTH AMERICAN HOLDINGS, INC.

By: \_\_\_\_\_  
Name:  
Title:

SHAREHOLDER REPRESENTATIVE SERVICES LLC, solely  
in its capacity as the Stockholder Representative

By: \_\_\_\_\_  
Name:  
Title:

**EXHIBIT A-1**

**Certificate of Incumbency  
(List of Authorized Representatives)**

Client Name: QIAGEN North American Holdings, Inc.

As an authorized officer of the above referenced entity, I hereby certify that each person listed below is an authorized signer for such entity, and that the title and signature appearing beside each name is true and correct.

<u>Name</u>	<u>Title</u>	<u>Signature</u>	<u>Contact Number*</u>	<u>Secondary Contact Number**</u>
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IN WITNESS WHEREOF, this certificate has been executed by a duly authorized officer on:\*\*\*

\_\_\_\_\_  
Date

By: \_\_\_\_\_  
Name:  
Title:

**EXHIBIT A-2****Certificate of Incumbency  
(List of Authorized Representatives)**

Client Name: Shareholder Representative Services LLC

As an authorized officer of the above referenced entity, I hereby certify that each person listed below is an authorized signer for such entity, and that the title and signature appearing beside each name is true and correct.

<u>Name</u>	<u>Title</u>	<u>Signature</u>	<u>Contact Number*</u>
Chris Letang	Managing Director	_____	303-957-2855
Eric Martin	Managing Director	_____	720-279-0974
Lon LeClair	Managing Director	_____	303-222-2078
Paul Koenig	Managing Director	_____	303-957-2850
Mark Vogel	Managing Director	_____	415-373-4020

*\*Please complete call-backs in the order indicated above (i.e., call Chris Letang first, Eric Martin second, etc.).*

As an authorized officer of the above referenced entity, I hereby certify that each person listed below is authorized to sign this Escrow Agreement on behalf of such entity, but is not authorized for providing any other direction on behalf of such entity to the Escrow Agent, and that the title and signature appearing beside each name is true and correct.

<u>Name</u>	<u>Title</u>	<u>Signature</u>	<u>Contact Number</u>
Sam Riffe	Executive Director	_____	720-279-0969
Radha Subramanian	Senior Director	_____	720-452-6253

IN WITNESS WHEREOF, this certificate has been executed by a duly authorized officer on:

\_\_\_\_\_  
Date

By: \_\_\_\_\_  
Its:



**EXHIBIT B**

Wire Instructions for Paying Account:

*[To be provided by Payments Administrator.]*

**EXHIBIT C**

The Parties authorize and direct the Escrow Agent to invest all deposits pursuant to this Escrow Agreement as follows:

**Escrow Fund:**

*Check one:*

- ☐ AXA Equitable Escrow Shield Plus
- ☐ SunTrust Non-Interest Deposit Option
- ☒ SunTrust Institutional Deposit Option

The investments in the SunTrust Institutional Deposit Option and the SunTrust Non-Interest Deposit Option are insured, subject to the applicable rules and regulations of the Federal Deposit Insurance Corporation (the "FDIC"), in the standard FDIC insurance amount of \$250,000, including principal and accrued interest, and are not secured. The SunTrust Institutional Deposit Option, SunTrust Non-Interest Deposit Option and AXA Equitable Escrow Shield Plus are more fully described in materials which have been furnished to the Parties, and the Parties acknowledge receipt of such materials. By electing the investment election above, the Parties hereby authorize the Escrow Agent to enter into any required documentation, on their behalf, to effect such investment election, consistent with the materials furnished to the Parties. Any investment earnings and income on funds held in the SunTrust Institutional Deposit Option shall become part of the account and shall be disbursed in accordance with this Escrow Agreement. Any investment earnings and income on funds invested in AXA Equitable Escrow Shield Plus shall become part of the account upon the final release of funds in the Escrow Fund and shall be disbursed in accordance with this Escrow Agreement.

QIAGEN North American Holdings, Inc.

Shareholder Representative Services LLC

By: \_\_\_\_\_  
Name:  
Title:

By: \_\_\_\_\_  
Name:  
Title:

**Exhibit D**

Form of Joinder Agreement

[see attached]

**EXHIBIT D****FORM OF JOINDER**

**THIS JOINDER** (this “Agreement”) is made and entered into as of the date set forth below by the person or entity whose name appears on the signature line to this Agreement (the “Holder”), pursuant to the Agreement and Plan of Merger, dated as of [•], 2018 (as amended, supplemented or otherwise modified from time to time, the “Merger Agreement”), by and among **QIAGEN NORTH AMERICAN HOLDINGS, INC.**, a California corporation (“Purchaser”); **NALEX MERGER SUB, INC.**, a Delaware corporation and a wholly owned Subsidiary of Purchaser (“Merger Sub”); **NEUMODX MOLECULAR, INC.**, a Delaware corporation (the “Company”); and **SHAREHOLDER REPRESENTATIVE SERVICES LLC**, a Colorado limited liability company, solely in its capacity as Sellers’ Representative (as more thoroughly defined in the Merger Agreement, the “Sellers’ Representative”). Unless the context requires otherwise, capitalized terms used but not defined herein shall have the meanings given to them in the Merger Agreement.

WHEREAS, pursuant to the Merger Agreement, Purchaser, Merger Sub, the Company and the Sellers’ Representative have agreed that Merger Sub will merge with and into the Company with the Company surviving the merger as the surviving corporation and a wholly owned subsidiary of Purchaser (the “Merger”);

WHEREAS, Holder owns such Company Capital Stock or Company Options as set forth in the Disclosure Schedules to the Merger Agreement; and

WHEREAS, as an inducement for Purchaser to consummate the Merger, the Holder is executing and delivering to Purchaser this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and certain other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Holder hereby agrees as follows:

**1. JOINDER**

**1.1** The Holder hereby acknowledges and agrees that he, she or it is a “Securityholder,” as defined in, and for all purposes of, the Merger Agreement and, accordingly, agrees to be bound by and comply with, the provisions of the Merger Agreement as fully as though Holder were an original signatory thereto, including, without limitation (i) with respect of Holders holding Company Capital Stock, the provisions of the Merger Agreement with respect to the treatment of Company Capital Stock and the consideration payable in respect thereof, in accordance with Section 2.5 of the Merger Agreement; (ii) with respect of Holders holding Company Options, the provisions of the Merger Agreement with respect to the cancellation of Company Options and the consideration payable in respect thereof, in accordance with Section 2.6 of the Merger Agreement; (iii) the rights of Purchaser, the Company, the Payments Administrator, the Escrow Agent, the Sellers’ Representative and their respective Affiliates to deduct and withhold, for tax purposes, certain amounts otherwise payable pursuant to the Merger Agreement as set forth in the Merger Agreement; (iv) the withholding of the Escrow Amount and Expense Fund from the Merger Consideration otherwise distributable to the Securityholders; (v) the agreement to be bound by and comply with the indemnification obligations set forth in Article VII of the Merger Agreement; (vi) the terms and conditions related to distributions to the Securityholders of amounts remaining, if any, from the Escrow Fund, and/or the Expense Fund as set forth in the Merger Agreement; and (vii) the designation of the Sellers’ Representative pursuant to Section 2.9 of the Merger Agreement.

**1.2** In furtherance and not in limitation of the foregoing, Holder (i) acknowledges the indemnification obligations of Holder pursuant to Article VII of the Merger Agreement, and agrees to be bound by and to perform all obligations applicable to a Seller and Option Holder, as applicable, thereunder, and agrees to indemnify the Purchaser Indemnified Persons in accordance with the terms and conditions of, and subject to the limitations (where applicable) set forth therein as fully as if Holder were an original signatory to the Merger Agreement, (ii) acknowledges and agrees that, in accordance with the provisions of the Merger Agreement, Purchaser will deposit with the Escrow Agent, the Escrow Amount to secure the indemnification obligations of the Sellers under Article VII of the Merger Agreement, and that Purchaser may receive payment for indemnified Losses from the Escrow Fund, (iii) acknowledges and agrees that Holder shall be entitled to a portion of the Escrow Fund, only if and when such amount is payable to Holder in accordance with the provisions of the Merger Agreement, (iv) acknowledges that the portion of any distribution from the Escrow Fund payable to Holder, if any, as calculated in accordance with the Merger Agreement, is a contingent right, and (v) acknowledges and agrees that subject to the terms and conditions of the Merger Agreement, the Purchaser Indemnified Persons may seek to recover for certain indemnification claims directly from Holder.

**1.3** Holder further acknowledges and agrees that (i) prior to the Closing, the Company will wire to the Sellers' Representative, the Expense Fund, which will be held by the Sellers' Representative as agent and for the benefit of the Holders in a segregated account and which will be used for the purposes of paying directly, or reimbursing the Sellers' Representative for, any third party expenses pursuant to this Agreement and the Ancillary Agreements, including legal fees and other post-Closing expenses incurred on behalf of the Securityholders, as approved by the Advisory Committee, (ii) as soon as practicable following the completion of the Sellers' Representative's responsibilities, the Sellers' Representative will deliver the balance of the Expense Fund to the Payments Administrator or the Company for distribution to the Securityholders, in a manner consistent with Schedule 2.5(d) of the Merger Agreement, and (iii) the portion of the Expense Fund payable to Holder, if any, is a contingent right.

## **2. ACKNOWLEDGMENT AND RELEASE**

**2.1** The Holder agrees that (a) the payments to be made pursuant to the Merger Agreement in exchange for the Holder's Company Capital Stock or Company Options, as applicable, shall constitute payment in full of all amounts to which the Holder may be entitled with respect to such securities in connection with the Merger and (b) the Holder, on behalf of himself, herself or itself and his, her or its Subsidiaries, Affiliates, employees, agents, advisors, heirs, legal representatives, successors and assigns (each, a "Releasor"), hereby irrevocably and unconditionally waives, releases and forever discharges, effective as of the Effective Time, to the fullest extent permitted by Law, Purchaser, the Company and their Affiliates and each of their respective current, former and future officers, directors, employees, agents, advisors, successors and assigns (collectively, the "Releasees") from any losses, Liabilities, suits, actions, debts or rights, whether fixed or contingent, known or unknown, matured or unmatured ("Claims"), relating to, arising out of or in connection with the Releasor's investment in the Company, and solely with respect to the Company's officers and/or employees, the Company, its business and/or its assets, or any Claims relating to, arising out of or resulting from the Releasor's status, relationship, affiliation, rights, obligations and/or duties as a director, officer, employee, optionholder or securityholder of the Company, for all periods through the time immediately prior to the Closing, except for Claims arising under the Merger Agreement or any Transaction Document (as defined in the Merger Agreement), and Claims by directors or officers for indemnification under the Company certificate of incorporation or by-laws or any contractual agreement with the Company regarding indemnification (collectively, the "Release of Claims").

**2.2** Effective as of the Effective Time, the Holder waives any rights the Holder might have under any applicable Law, statutory or otherwise, intended to protect the Holder from releasing or waiving unknown claims.

**2.3** The Holder hereby irrevocably covenants to refrain from, directly or indirectly, asserting any claim or demand, or commencing, instituting or causing to be commenced or instituted any Claim released pursuant to Section 2.1, of any kind against any Releasees before any court, administrative agency or other forum with respect to or by reason of any matters released hereby.

### **3. WAIVERS**

**3.1** The Holder hereby irrevocably waives any rights to appraisal of the fair value of the Holder's shares of Company Capital Stock owned or held, together with any rights to dissent from the Merger that the Holder may have, pursuant to Section 262 of the DGCL or otherwise.

**3.2** As of the Effective Time, the Holder hereby irrevocably waives any and all notice, consent, preemptive, first offer, first refusal or other similar rights to which the Holder may be entitled, including any such rights granted under the Certificate of Incorporation of the Company.

### **4. REPRESENTATIONS AND WARRANTIES**

**4.1** Holder hereby represents and warrants that the Disclosure Schedule to the Merger Agreement sets forth all of the Company Capital Stock and/or Company Options beneficially owned by Holder as of the date of this Agreement.

**4.2** The Holder hereby represents and warrants that this Agreement has been duly executed and delivered by the Holder and constitutes the authorized (if applicable), valid and binding obligation of the Holder, enforceable in accordance with its terms.

**4.3** The Holder hereby represents and warrants that the Holder has access to adequate information regarding the scope and effect of this Agreement to make an informed and knowledgeable decision with regard to entering into this Agreement. The Holder hereby further represents and warrants that he, she or it has not relied upon the Company or Purchaser in deciding to enter into this Agreement and has instead made his, her or its own independent analysis and decision to enter into this Agreement.

**4.4** The Holder hereby represents and warrants that the Holder (a) has not assigned or transferred or purported to assign or transfer to any Person all or any part of, or interest in, any Claim or possible Claim and the Holder has no pending Claims, (b) fully intends to release all Claims, (c) has read and understands this Agreement, has had the opportunity to consult with counsel with respect to the execution and delivery of this Agreement and voluntarily enters into this Agreement with full knowledge of its terms and conditions and that such terms and conditions are binding on the Holder, (d) has entered into such Release of Claims freely, and (e) acknowledges that it would be difficult to fully compensate Purchaser or any of its Affiliates for damages resulting from any breach of the provisions of such Release of Claims.

**4.5** The Holder hereby represents and warrants that it is not relying upon any information, other than as expressly set forth in this Agreement or the Merger Agreement or any agreements ancillary thereto.

### **5. MISCELLANEOUS**

**5.1 Specific Enforcement.** The Holder agrees and understands that monetary damages would not adequately compensate the Company, Purchaser, Merger Sub, and Sellers' Representative for the breach of this Agreement by the Holder, that this Agreement shall be specifically enforceable and that any breach or threatened breach of this Agreement shall be the proper subject of a



temporary or permanent injunction or restraining order. Further, the Holder waives any claim or defense that there is an adequate remedy at law for such breach or threatened breach.

**5.2 Amendments and Waivers.** Except as set forth otherwise herein, any term hereof may be amended and the observance of any term hereof may be waived (either generally or in a particular instance and either retroactively or prospectively) only with the written consent of both the Holder and Purchaser.

**5.3 Captions.** The captions, headings and arrangements used in this Agreement are for convenience only and do not in any way limit or amplify the terms and provisions hereof.

**5.4 Severability.** Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement shall be held to be prohibited by or invalid under applicable Law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

**5.5 Assignment; Binding Effect; Rights of Third Parties.** Neither the Holder nor any of the parties hereto (the "Parties") shall assign this Agreement or any of their rights or obligations hereunder without the prior written consent of Purchaser or the Holder, respectively, except that the rights of Purchaser and Merger Sub hereunder may be assigned without consent to any Person to whom their respective rights under the Merger Agreement may be assigned without consent. Subject to the foregoing, this Agreement shall be binding upon the Holder and his, her or its heirs and permitted successors and assigns, as applicable. This Agreement shall also be binding upon and inure to the benefit of each of the Company, Purchaser, Merger Sub, Sellers' Representative and their respective heirs, successors and assigns. In addition, this Agreement shall be binding with respect to all Company Capital Stock and Company Options held by the Holder as of the Closing Date.

**5.6 Governing Law.** This Agreement and all claims or causes of action (whether sounding in contract or tort) arising under or related to this Agreement, shall be governed by and construed in accordance with, the Laws of the State of Delaware, without regard to any rule or principle that might refer the governance or construction of this Agreement to the Laws of another jurisdiction.

**5.7 Exclusive Jurisdiction; Venue; Service of Process.** In any action or proceeding between any of the Parties arising under or related to this Agreement, each of the Parties (a) knowingly, voluntarily, irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the Court of Chancery of the State of Delaware or to the extent that such court does not accept jurisdiction, the Superior Court of the State of Delaware or the United States District Court for the District of Delaware, (b) agrees that all claims in respect of any such action or proceeding shall be heard and determined exclusively in accordance with clause (a) of this Section 5.7, (c) waives any objection to the laying of venue of any such action or proceeding in such courts, including any objection that any such action or proceeding has been brought in an inconvenient forum or that the court does not have jurisdiction over any Party and (d) agrees that service of process upon such Party in any such action or proceeding shall be effective if such process is given as a notice in accordance with Section 8.2 of the Merger Agreement. The Parties agree that any Party may commence a proceeding in a court other than the above-named courts solely for the purpose of enforcing an order or judgment issued by one of the above-named courts.

**5.8 JURY TRIAL.** EACH OF THE PARTIES KNOWINGLY, VOLUNTARILY, IRREVOCABLY AND UNDER THE PROFESSIONAL ADVICE OF COUNSEL WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY WITH RESPECT TO ANY LEGAL ACTION OR PROCEEDING DIRECTLY OR



INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT BETWEEN ANY OF THE PARTIES.

**5.9 Further Assurances.** The Holder shall, from time to time, execute and deliver or cause to be executed and delivered such instruments and shall take or cause to be taken such further action as Purchaser shall reasonably request or as shall be necessary for the purpose of effectively carrying out the transactions contemplated by this Agreement, including, if applicable, obtaining the Holder's spouse's acknowledgment of and consent to the existence and binding effect of this Agreement through execution and delivery of a spousal consent in a form reasonably acceptable to Purchaser if any shares of Company Capital Stock or Company Option held by the Holder constitute the community property of the Holder and his or her spouse.

**5.10 Entire Agreement.** This Agreement, along with the Merger Agreement and any agreements ancillary thereto, is intended to be the sole agreement of the Holder as it relates to this subject matter and hereby and supersedes all other agreements of the Holder relating to the subject matter hereof.

**5.11 Termination.** This Agreement shall terminate upon the termination of the Merger Agreement in accordance with the terms thereof.

**5.12 Purchaser as Beneficiary.** The Holder hereby agrees that the Purchaser and its Affiliates will be direct beneficiaries of the covenants made in this Agreement and entitled to enforce the provisions of this Agreement against the Holder, including, without limitation, with respect to any breach or threatened breach of the Merger Agreement.

*[Remainder of page intentionally left blank.]*

IN WITNESS WHEREOF, the Holder has caused this Agreement to be executed and delivered as of the date first written above.

Dated: \_\_\_\_\_, 2018

FOR INDIVIDUAL:

Please Sign: \_\_\_\_\_

Print Name: \_\_\_\_\_

FOR ENTITY:

\_\_\_\_\_  
*(Name of Corporation, Trust or other Entity)*

By: \_\_\_\_\_

Name:

Title:

[Joinder]